S. HRG. 99-731

HUMAN RESOURCES IMPACT: OVER-THE-COUNTER PRODUCT PACKAGING SAFETY

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

REVIEWING THE EFFECTIVENESS OF CURRENT PACKAGING AND SAFETY REGULATIONS GOVERNING OVER-THE-COUNTER PRODUCTS

FEBRUARY 28, 1986

Printed for the use of the Committee on Labor and Human Resources

U.S. GOVERNMENT PRINTING OFFICE
60-675 O
WASHINGTON : 1986

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, DC 20402

S541-65

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HUMAN RESOURCES IMPACT: OVER-THE-COUNTER PRODUCT PACKAGING SAFETY

FRIDAY, FEBRUARY 28, 1986

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 9:32 a.m., in room SD-430, Dirksen Senate Office Building, Senator Orrin Hatch (chairman) presiding.

Present: Senators Hatch, Stafford, Thurmond, Grassley, Kennedy, and Metzenbaum.

OPENING STATEMENT OF SENATOR HATCH

The CHAIRMAN. We are happy to call this Labor Committee hearing together on human resources impact of over-the-counter package safety.

In 1982, American consumers were jolted into a rude awakening. They could no longer take for granted that the packaging of over-the-counter health products would protect the contents from contamination or malicious tampering. Seven deaths proved that tampering, which had previously been considered only in the realm of possibility, had become a probability and, in fact, a reality.

An individual or group of individuals had devised a method of adding poison that avoided easy detection to an over-the-counter medication, Tylenol capsules. This reprehensible event alerted the public to inspect over-the-counter goods for signs of tampering; it was the catalyst for new Food and Drug Administration regulations requiring tamper-resistant packaging, and it revealed that an industry can move quickly to meet the burden of ensuring the safety of its products.

Nevertheless, we meet here today with the knowledge that another young woman is dead because the Tylenol capsule she took had been laced with cyanide. Just this week, it was reported that a man in Tennessee may have met a similar fate. Although an autopsy revealed that his body contained a lethal dose of cyanide, it has not been determined if his death was due to the ingestion of altered capsules or self-induced.

Dr. Young will have a statement on that situation this morning.

What has become crystal clear is the fact that even though over-the-counter packaging has been made tamper-resistant, it is not tamperproof. This fact was made known in 1982, but I do not think it was fully appreciated by the general public. I think it is also established that some forms of medication may be more susceptible to tampering than others, though perhaps we might ultimately find that some can be made risk-free.

I am certain that everyone here shares my belief that our paramount concern is the health and safety of the American consumer. While law enforcement officials pursue the culprit or culprits responsible for these heinous actions, the members of this committee, the Federal Government and those in the industry must tackle the important health questions that relate to the effectiveness of current packaging and safety regulations governing over-the-counter products.

We will ~~hear~~ today from the Food and Drug Administration about the role of the Government in these situations and the scientific and technological protections which are built into their processes. Most importantly, we will hear from consumers, the intended victims of these acts.

What should we do to address the concerns which these incidents create? What do the consumers expect from industry? Do they want increased Government intervention? Do they want further action from industry? And what intrusions, if any, do consumers want in the free marketplace in response to these acts?

These questions and their answers will go beyond the traditional safety and effectiveness criteria upon which pre-marketing approvals are based. The questions and their answers must address the restoration of consumer confidence; the susceptibility of some products to tampering; dosage forms; new technologies in packaging; and distribution methods.

Upon obtaining the answers and reviewing the recommendations, we and the industry, in particular, must have the will and the resolve to take the necessary and appropriate steps. I cannot overemphasize that point because knowing the right thing to do and actually doing it are two different things. As always, however, those of us in Government must be diligent, but should not act precipitously and without deliberation.

It is significant to note that currently there are more than 300,000 over-the-counter medicines marketed in the United States and billions of packages sold annually. These beneficial medications are used by millions of men, women and children; my family and I included who, on occasion, experience some discomfort from headaches, sore throats, the flu, and a host of other ailments.

Quite frankly, I think all consumers—you and I—feel compassion for the victims, their families, friends, and communities. We also share a sense of outrage and downright disgust in knowing that somebody is attempting to create havoc with the supply of these common remedies. It is shameful that these senseless acts have now caused concern with not just the quality of these products but their safety as well.

Over-the-counter drugs play an integral role in America's health care system. For the most part, they are inexpensive and can be conveniently obtained in stores across the Nation. It has been estimated that if these products are no longer available, the resulting patient load in doctor, offices, emergency rooms and clinics could possibly disrupt our health care system. Clearly, this is not our goal.

Therefore, it is incumbent upon us to put these known cases of tampering in perspective. It is believed that the incidents in 1982 involved five bottles of Tylenol capsules that were criminally tampered with, a total of 44 capsules. The incident in Westchester County is believed to be limited to two bottles and five capsules. As I indicated earlier, I am not certain if the FBI has determined whether the death in Tennessee is also related to Tylenol tampering; and, if it is, I am certain Commissioner Young and Mr. O'Hara will comment on that in their testimony.

[Information supplied follows:]

STATEMENT BY THE FOOD AND DRUG ADMINISTRATION
FOR IMMEDIATE RELEASE

Feb. 10, 1986
Bill Grigg (301) 443-4177
Home (301) 652-1864

The Food and Drug Administration is investigating, along with local law enforcement officers, the death of a woman, 23, from cyanide poisoning.

The woman allegedly had taken Tylenol capsules.

In the past, such incidents have invariably proved local in nature. FDA advises that residents in the Yonkers, N.Y., area should avoid taking Tylenol capsules, until more is known. As a special precaution, FDA further advises consumers to avoid lot code ADF916, expiration date 5/87. The lot has been in distribution since August 1985, without known incident.

Questions about the death and the local situation should be addressed to the Yonkers City Police Department in New York. Tylenol capsules have been removed from an A&P supermarket in Bronxville, N.Y., where the capsules taken by the woman were allegedly purchased. As a precaution, A&P is also removing the capsules from other stores in the area.

Preliminary analysis from remaining stock in the store where the Tylenol was allegedly purchased reveals no indication of further tampering.

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Note: Further updates on this situation will be made available as soon as they are known.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P86-8
FOR IMMEDIATE RELEASE
February 13, 1986

Food and Drug Administration
William Grigg - (301) 443-3285
(Home) -- (301) 652-1864

FDA Commissioner Frank E. Young warned tonight that consumers nationally should completely avoid Tylenol capsules of ALL lot numbers and strengths until further notice. The scientists at FDA's New York laboratories (Brooklyn) late this afternoon found cyanide in five capsules in a single bottle of Extra Strength Tylenol. Because this lot, AHA090, was different from the previous lot containing cyanide, ADF916, consumers should completely avoid all Tylenol capsules in any strength in any lot until further notice. Even though this still appears to be a local occurrence in the greater New York area, all consumers should, as an extra precaution, remove all Tylenol capsules from medicine cabinets to avoid use by children and family members. The newly discovered bottle was found at a non-A&P store in the same general vicinity of the A&P store that the bottle of Extra Strength Tylenol implicated in the death of Diane Elsroth was reportedly purchased.

The CHAIRMAN. What I am trying to point out is that there does not appear to be a widespread phenomenon of tampering; however, just one incident is enough to require a serious reevaluation of our efforts.

Our purpose today is not to point fingers, absolve any institution or organization from responsibility, or merely say keep up the good work. The reason for this hearing is to find out what has been done, what is being done now, and what will be done to make sure that over-the-counter products remain available to the public and that industry does all it possibly can to assure those products are reasonably safe from the "would-be" tamperer.

I would like to welcome the five panels of expert witnesses who will give testimony at today's hearings and thank them for agreeing to be here on such short notice. Our first witness was to be Mr. James E. Burke, chairman of the board of Johnson & Johnson. We learned late last night Mr. Burke has the flu and will be unable to join us today. We know if it were at all possible, he would be here. David Clare, president of Johnson & Johnson worldwide, and chairman of the executive committee will be joining us. As President, Mr. Clare is playing an integral part and providing thoughtful leadership in the efforts and commitments of Johnson & Johnson to fulfill its responsibility to consumers and corporate morality.

Our second panel consists of Frank E. Young, Commissioner of the Food and Drug Administration; Nicholas O'Hara, chief, General Crimes Section of the Criminal Investigation Division of the Federal Bureau of Investigation; and Carol Dawson, acting chairman of the Consumer Product Safety Commission.

Our third panelist is Arthur Hull Hayes, dean and provost, New York Medical College and former Commissioner of the Food and Drug Administration.

The fourth panel, intended to help bring consumer views into focus, will consist of Nancy Harvey Steorts, a former Chairman of the Consumer Product Safety Commission; Dr. Monroe Gilmour, American Association of Retired Persons accompanied by Ms. Judith Brown, also of AARP. Ms. Odonna Mathews, vice president of consumer affairs at Giant Food Corp. will also be on this panel.

On the fifth and final panel are James Cope, president of the Proprietary Association, who will be accompanied by Daniel O'Keefe, Jr., vice president and general counsel, and Dr. R. William Soller, vice president of scientific affairs; and Mr. Peter Fink, president and chief executive officer of R. P. Scherer Corp., who will bring us information of important capsule technology.

That will conclude our witnesses for today.

With that, let me turn to Senator Kennedy.

Senator KENNEDY. Thank you very much, Mr. Chairman.

First of all, I want to express our appreciation to you for holding these extremely important and significant hearings on an issue of enormous concern to millions of Americans.

Every day there are millions of Americans who go to their drug stores or go to their supermarkets and buy the over-the-counter pain relievers. I believe that those consumers want to know—and hopefully this hearing can shed some light on—when they go into those drugstores and supermarkets and pick off the shelf the pain relievers, how safe are they?

Are they somewhat safe? Are they very safe?

We all recognize the extraordinary tragedy of eight individuals who have died as the result of lacing the Tylenol product with a deadly poison. Certainly one of the other casualties of this whole tragedy is the anxiety that is being caused all across our country.

Perhaps as a result of this hearing we can provide some information to millions of Americans on this very important and significant issue.

Second, I would hope that as a result of this hearing we would have gained some idea of whether the state of the art, so to speak—whether everything that can be done is being done or whether it should be done. I think consumers are going to ask: Is everything being done that possibly can be done? And, are the various agencies of Government requiring that?

We want to explore that issue here this morning here, as well.

I think also we are going to welcome the Federal Bureau of Investigation to our hearing this morning. Obviously, we are not interested in interfering with the legitimate investigation and, hopefully, the prosecution of a deranged and mad mind that, I believe, is a kind of a terroristic act here in our own society.

But we want to know if the information that they have, that does not inhibit that investigation, should not be made public so that the American consumer, again, and we in the Congress that are attempting to insure the safety and efficacy and the whole questions of the use of our drug supply in our society are going to be protected.

So this is an important hearing, Mr. Chairman. I welcome the opportunity, as well, to thank the witnesses for joining with us this morning and hope that they will address those issues, as well as other issues, in the course of the morning's deliberations.

Thank you, Mr. Chairman.

[The prepared statement of Senator Kennedy follows:]

from the office of
Senator Edward M. Kennedy
of Massachusetts

STATEMENT BY SENATOR EDWARD M. KENNEDY
OTC PRODUCT SAFETY
February 28, 1986

A young woman in New York is dead, the victim of a second round of Tylenol poisonings. A young man in Tennessee may also be a victim of cyanide, cyanide in a pain-relief capsule. And, only through swift action was another bottle of poisoned Tylenol discovered before it reached an innocent consumer.

It is an evil irony that the same drugs that relieve pain are now a sure cause of anxiety, and that their packages remain a possible weapon for murder. And, it is especially disturbing that this round of Tylenol poisonings occurred after the wave of deaths in Chicago. After that crisis, industry and government fashioned what the consumer thought were sufficient safeguards to prevent the present tragedy.

We will inquire today into the safety of the over-the-counter drug supply. Are current controls adequate? Are capsules more vulnerable to terrorist tampering?

We will inquire today into the government investigations to find the party responsible for the Tylenol murders. We will inquire into the efforts of industry and government regulators to prevent such poisonings. And we will inquire into government's and industry's responsibility in the future to protect consumers from unsafe food and drugs, whether the poison in the package is there as a result of an avoidable contamination, a malicious employee, or a clever murderer.

This crime raises other larger questions about the public safety.

New technologies must be developed that reduce the opportunity for malicious tampering. The public must be protected against such acts of terrorism. Part of our job here this morning is to ensure that it is.

##

The CHAIRMAN. Well, thank you, Senator Kennedy.

Senator Stafford.

Senator STAFFORD. Thank you very much, Mr. Chairman.

I think the entire matter has been so thoroughly stated by you and by Senator Kennedy that it would be redundant on my part to go over the scene again. I have followed the trials and tribulations of Johnson & Johnson with respect to Tylenol fairly closely because Mr. Jim Burke—who had, without becoming ill, intended to be here—is from the same hometown in Vermont, Rutland, that I am. So we natives of that little city have followed his career in Johnson & Johnson with a great deal of interest.

Having said that and expressing the hope that he will soon be well enough to resume his duties, I am looking forward to the testimony of witnesses this morning.

I will yield back the floor.

The CHAIRMAN. Thank you, Senator Stafford.

Senator Metzenbaum.

Senator METZENBAUM. I have no statement.

The CHAIRMAN. Thank you, Senator.

Senator Thurmond.

Senator THURMOND. Thank you, Mr. Chairman.

Mr. Chairman, it is indeed tragic that recent events have made the subject of this hearing such an important issue. However, Mr. Chairman, I am pleased that you have recognized the great concern the citizens of our Nation have demonstrated for the safe packaging of over-the-counter drugs and have scheduled this hearing.

I have had a long interest in this matter. In the 98th Congress, I offered, along with some others, S. 216, the Federal Anti-Tampering Act. This legislation was introduced in response to the 17 deaths in Chicago resulting from the poisoning of Tylenol capsules.

It was signed into law in late-1983 and provides stiff criminal penalties for those who tamper with consumer products. If death results from criminal tampering, the statute provides for up to $100,000 in fines and for life imprisonment.

I want this message to get out over the country that this statute is a tough statute and anyone found guilty of violating it—I repeat and hope the TV will carry it, and all who are thinking about tampering these things will hear this—can be fined up to $100,000 and be given life imprisonment.

Mr. Chairman, I am confident that reputable companies, such as Johnson & Johnson, endeavor to take every reasonable precaution to prevent tampering with their consumer products. Despite such efforts, there are deranged individuals in our society who go to great lengths to harm others.

Hopefully, this hearing will teach us more about what can be done to prevent the recurrence of such tragedies.

I want to welcome Commissioner Young here this morning, and Ms. Steorts and the other distinguished witnesses who will testify. I understand Mr. Burke is ill and cannot be here.

Unfortunately, a prior scheduling conflict will not permit me to remain for the entire hearing, but I shall look forward to reviewing the testimony which will be presented here this morning and feel it could be very important to the American public.

Thank you, Mr. Chairman.

The **Chairman**. Thank you, Senator. We appreciate you, as chairman of the Judiciary Committee, bringing out the legalities involved.

[We will receive for the record a statement from Senator Grassley at this time:]

United States Senate

COMMITTEE ON LABOR AND
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WASHINGTON, DC 20510

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STATEMENT BY SENATOR CHARLES E. GRASSLEY BEFORE THE COMMITTEE ON LABOR AND HUMAN RESOURCES ON OTC PRODUCT PACKAGING SAFETY, FRIDAY FEBRUARY 28, 1986.

Thank you Mr. Chairman. I appreciate the opportunity to participate in this hearing.

I think that it's important for those consumers who use over-the-counter products to have available the kind of systematic review, by individuals intimately involved with producing over-the-counter products and by individuals closely involved with regulating the production and marketing of such products, that we should get through this hearing today.

I think also that it's important for us in the Congress to review the steps being taken with respect to over-the-counter drug product safety and with respect to consumer education, so we can determine whether we are doing enough in these areas. It certainly seems possible that the kind of tragic events we saw earlier this month could happen again, and therefore we really must be certain that we are doing all that is humanly possible to prevent such a reoccurance.

Thank you Mr. Chairman. I look forward to hearing the testimony.

The CHAIRMAN. We will state at the outset of the hearing that we will place all written testimonies into the record as though fully delivered. We prefer summarizations and we would like every witness to keep his testimony as short as he possibly can. We would like it to be 5 minutes, but no more than 10.

At this point, we will call on Mr. David R. Clare, president of Johnson & Johnson and chairman of the corporation's executive committee.

Mr. Clare, we will be happy to take your testimony at this time.

STATEMENT OF DAVID R. CLARE, PRESIDENT AND CHAIRMAN OF THE EXECUTIVE COMMITTEE OF JOHNSON & JOHNSON

Mr. CLARE. Thank you for the opportunity to testify, Mr. Chairman. As you have mentioned, our chairman, Jim Burke, is unavailable due to illness. I will present our statement.

I will begin by describing the chronology of the Westchester County incidents in as succinct a fashion as possible.

On Monday afternoon, February 10, we were informed that a young woman, Dianne Elsroth from Westchester County, NY, died of cyanide poisoning after ingesting Tylenol Extra-Strength capsules. We immediately sent representatives to Yonkers to attempt to learn more and to assist in the investigation.

We also began, immediately, conferring by telephone with the FDA and the FBI both in Washington and at the responsible field offices. We publicly endorsed the recommendation of the FDA and local authorities that people in the Bronxville-Yonkers area not take any of the capsules until the investigation was completed.

Although from the outset we had no reason to believe that this was more than an isolated event, we also concurred in the FDA recommendation that, nationally, no one take any capsules from the affected lot number until further notice. We asked consumers and the trade to return products from this lot for credit or exchange.

We responded to hundreds of news media inquiries providing up to the minute information, and we also held three major press conferences in a week's time. These conferences were carried to the news media nationwide via satellite and special phone lines.

We established a free 800 telephone hotline through which consumers and retailers could contact McNeil Consumer Products Co. to receive the latest information and advisories, and we suspended all television advertisements for the product as of the evening of February 10.

On Tuesday, February 11, we initiated a pickup of the entire Tylenol capsule inventory from all retail outlets in a 3-mile radius of the store where it is believed that the bottle of poisoned capsules was purchased. Laboratories of the FDA and McNeil Consumer Products Co. began chemical analyses of capsules retrieved from the Westchester County area by each organization.

Additionally, as we did in 1982, we began polling consumers through independent research organizations to track their awareness and understanding of the extent of the problem and attitudes toward our products. On the same afternoon, of February 11, we called a news conference to aid in the accuracy of the information communicated to the public and to make certain that they were aware of the nature of the problem.

In the samples picked up and analyzed by the FDA, a second bottle was identified that contained five capsules of cyanide. This was on Thursday, February 13. Within minutes of notification to us that the FDA had found this second bottle, we issued a nationwide release to the news media warning all consumers not to use Tylenol capsules until further notice. This was supportive of the FDA's own release.

On the evening of the 13th, we initiated a withdrawal of capsule put-ups from wholesalers, retailers, and consumers in the Westchester County area. We also began the process of notifying the trade nationwide to remove Tylenol capsule put-ups from their shelves.

At our second news conference, on Friday, February 14, we publicly urged consumers, nationwide, to stop taking Tylenol capsules. We offered to replace them with caplets or tablets if they were concerned, and we urged the trade nationwide to remove Tylenol capsules from their shelves.

Further, we offered a reward of $100,000 for information leading to the identification of the person or persons responsible for the poisoning of the capsules in Westchester County.

During exhaustive deliberations over the weekend of February 15 and 16, we concluded that the company could no longer guarantee the safety of capsules to a degree consistent with Johnson & Johnson's standard of responsibility to its consumers. Thus on Monday, February 17, we announced at our third press conference that Johnson & Johnson will no longer manufacture or sell any capsule products made directly available to the consumer; and that we had no plans to re-enter this business for the foreseeable future.

We were aided in this judgment by the knowledge that we had the caplet available, a solid dosage form that all our research showed was an acceptable alternative to a majority of our capsule users. We also announced, on February 17, we would replace all capsules in the hands of consumers in the trade with caplets or tablets.

To date, the combined efforts of law enforcement agencies, the Food and Drug Administration and our company have not been able to establish precisely where the tampering occurred. It is our belief, however, it occurred after the product left our facilities.

The FBI's recent statement, that it had discovered evidence that the bottles were, in fact, tampered with, tends to support our conviction that the contamination did not occur during manufacturing.

The Tylenol which was purchased in the Bronxville A&P was manufactured in Fort Washington, PA, in May of 1985. It was shipped to our distribution center in Montgomeryville, PA, on August 21, 1985, and, from there, on the next day to an A&P company warehouse in Dunmore, PA.

From Dunmore, it was shipped to a second A&P warehouse in Edison, NJ; and, finally, to the Bronxville A&P store.

The bottle found in the Bronxville Woolworth store was manufactured in McNeil's Puerto Rico facility on July 16, 1985. It was shipped as part of a lot received in Montgomeryville on September

5 and 6, and from there it was shipped to Woolworth's distribution center on September 6 and then on to the store in Bronxville.

Our records show that these bottles were never in the same manufacturing facility or same distribution center at the same time.

To date, almost 2 million capsules have been examined by the FDA and our laboratories. With the exception of the very recent Tennessee event of yesterday, which appears to be an unrelated event of entirely different nature, no additional tainted capsules have been discovered.

This reinforces our belief that the tamperings did not occur in our facilities. For this to have occurred, the two Bronxville bottles, manufactured in different locations at different times traveling in random distribution patterns to different retail outlets, would have had to complete the process at virtually the same time only 1½ blocks apart.

Based on these facts, we do not believe that the tampering could have occurred in our facilities; but until the criminal responsible is found, we will not have proven where it did occur.

After the tampering in the Chicago area in the fall of 1982, our company conducted an exhaustive review of virtually every viable technology. Ultimately, we selected, for Tylenol capsules, a triple safety sealed system that consists of glued flaps on the outer box, a tight printed plastic seal over the cap and neck of the bottle, and a strong foil seal over the mouth of the bottle.

Our decision to reintroduce capsules was based on marketing research done during that time. This research indicated that the capsules remained the dosage form of choice for many consumers. Many felt it was easier to swallow and some felt that it provided more potent pain relief.

While there is no basis in fact for this latter perception—tablets, caplets, and capsules are all equally effective—it is not an irrelevant consideration. To the extent that some people think a pain reliever may be more powerful, a better result can often be achieved.

This is due to a placebo effect, but it is nonetheless beneficial to a consumer.

Given these findings and our confidence in the new triple-sealed packaging system, we made the decision to reintroduce Tylenol Extra-Strength pain relievers in capsule form.

Clearly, circumstances are different today. In light of the Westchester events, we no longer believe that we can provide an adequate level of assurance of the safety of hollow capsule products sold directly to consumers.

For this reason, we made the decision to go out of that business. We will encourage consumers to use either the solid tablets or caplets. The caplet is especially well suited to serve the needs of capsule users in that it's ovalshaped like a capsule, 35 percent smaller and coated to facilitate swallowing.

It is also hard like a tablet and thus far more difficult to violate without leaving clearly visible signs.

We developed this dosage form as an alternative to the capsule. Since its introduction in 1984, it has become the analgesic dosage form of choice for many consumers.

Mr. Chairman, during both the Chicago and Westchester tampering events, we have been deeply impressed by the commitment and performance of Government agencies, especially the FDA and the FBI. We cannot imagine how any organizations could have been more professional, more energetic, or more rational in exercising their responsibilities to the American public.

In addition, the media performed an invaluable role in telling the public what they needed to know in order to provide for their protection. This was accomplished swiftly and, in the overwhelming majority of instances, accurately.

Our poll showed that within the first week following the Westchester event 96 percent of consumers in America were aware of the problem. As was the case in Chicago, this is an example of how the media performs an invaluable service when the public safety is at issue.

The wide availability of self-medications through the open market in the United States is an important part of our unique health care delivery system. We must work together to maintain the advantages of the system.

For industry and Government, this means doing what is appropriate to provide for the safety of consumer products.

At the same time we must assure the freedom to take full advantage of an open marketplace, not the least of which is enlightened product selection at a reasonable cost. For the consumer, this means education and awareness.

As has often been noted, no system yet designed can guarantee freedom from product tampering. Careful consumers must be the most important element in providing for their own safety.

Thank you. That concludes our statement.

The CHAIRMAN. Well, thank you, Mr. Clare.

[The prepared statement of Mr. Burke follows:]

Statement of

JAMES E. BURKE
Chairman, Board of Directors
and
Chief Executive Officer
Johnson & Johnson

Presented to
U. S. Senate Committee on Labor and Human Resources
Friday, February 28, 1986

Mr. Chairman, thank you for the opportunity to testify before you today.

My name is James E. Burke. I am Chairman of the Board of Directors and Chief Executive Officer of Johnson & Johnson. I am accompanied by David R. Clare, President of Johnson & Johnson and Chairman of our Executive Committee. Johnson & Johnson is a diversified international health care corporation. One of our subsidiaries, McNeil Consumer Products Company, manufactures TYLENOL* brand analgesic products for direct sale to consumers.

My statement will focus on four areas: a brief chronology of the tragic events that occurred in Westchester County, New York, subsequent to February 8, 1986 and the actions that followed; the distribution patterns for the two TYLENOL* Extra-Strength capsule bottles involved in the Westchester tamperings; comments on the development of tamper-resistant packaging following the cyanide poisonings in Chicago in

September 1982; and our recent decision to discontinue the manufacture, distribution and sale of capsule products made directly available to the consumer.

CHRONOLOGY

I will begin by describing the chronology of the Westchester County incidents in as succinct a fashion as possible.

On Monday afternoon, February 10, we were informed that a young woman in Westchester County, New York, died of cyanide poisoning after ingesting TYLENOL* Extra-Strength capsules.

We immediately sent representatives to Yonkers to attempt to learn more and to assist in the investigation. We also began immediately conferring by telephone with the FDA and the FBI both in Washington and at the responsible field offices.

We endorsed the recommendation of the FDA and local authorities that people in the Bronxville/Yonkers, N.Y. area not take any of these capsules until the investigation was completed.

Although from the outset we had no reason to believe that this was more than an isolated event, we also concurred in the FDA recommendation that nationally no one take any capsules from the affected lot number -- ADF 916 -- until further notice. We asked consumers and the trade to return product from this lot for credit or exchange.

We responded to hundreds of news media inquiries, providing up-to-the-minute information, and we also held three major press conferences in a week's time at our headquarters. These press conferences were carried to the news media nationwide via satellite and special phone lines. We established a free, "800" telephone hotline through which consumers and retailers could contact McNeil Consumer Products Company to receive the latest information and advisories. And we suspended all television advertisements for the product as of the evening of February 10.

On Tuesday, February 11, we initiated a pick-up of the entire TYLENOL* capsule inventory from all retail outlets in a three-mile radius of the store where it is believed the bottle of poisoned capsules was purchased. Laboratories of the FDA and McNeil Consumer Products Company began chemical analyses of capsules retrieved from the Westchester County area by each organization. Additionally, as we did in 1982, we began polling consumers through independent research organizations to track their awareness and understanding of the extent of the problem and attitudes toward our products.

On the afternoon of February 11th, we called a news conference to aid in the accuracy of the information communicated to the public and to make certain that they were aware of the nature of the problem.

In the samples picked up and analyzed by the FDA a second bottle was identified that contained five capsules of cyanide. This was on Thursday, February 13.

Within minutes of notification to us that the FDA had found this second bottle of contaminated capsules, we issued a nationwide release to the news media warning all consumers not to use TYLENOL* capsules until further notice. This was supportive of the FDA's own release. On the evening of the 13th, we initiated a withdrawal of capsule put-ups from wholesalers, retailers and consumers in the Westchester County area. We also began the process of notifying the trade nationwide to remove TYLENOL* capsule put-ups from their shelves.

At our second news conference on Friday, February 14, we publicly urged consumers nationwide to stop taking TYLENOL* capsules; we offered to replace them with caplets or tablets if they were concerned; and we urged the trade nationwide to remove TYLENOL* capsules from their shelves. Further, we offered a reward of $100,000 for information leading to the identification of the person or persons responsible for the poisoning of TYLENOL* capsules in Westchester County.

During exhaustive deliberations over the weekend of February 15 and 16 we concluded that the company could no longer guarantee the safety of capsules to a degree consistent with Johnson & Johnson's standards of responsibility to its consumers. Thus on Monday, February 17, we announced at our third press conference that Johnson & Johnson will no longer manufacture or sell any capsule products made directly available to the consumer, and that we have no plans to reenter this business for the foreseeable future. We were aided in this judgment by the knowledge that we had the caplet available, a solid dosage form that all our research showed was an acceptable alternative to the majority of our capsule users.

We also announced on February 17 that we would replace all capsules in the hands of consumers and the trade with caplets or tablets. . . we issued a toll-free 800 number consumers could call for a product exchange or a full refund. . . and we announced a TYLENOL* capsule exchange address.

DISTRIBUTION PATTERNS

To date, the combined efforts of law enforcement agencies, the Food and Drug Administration and our company have not been able to provide any explanation of how or where the tampering occurred. It is our belief, however, that the tampering occurred after the product left our facilities.

→ The TYLENOL* bottle which was purchased in the Bronxville A&P was manufactured in Fort Washington, Pennsylvania, in May, 1985. It was shipped to our distribution center in Montgomeryville, Pennsylvania, on August 21, 1985, and from there to an A&P Company warehouse in Dunmore, Pennsylvania.

From Dunmore it was shipped to a second A&P warehouse in Edison, New Jersey, and finally to the Bronxville A&P store.

The bottle found in the Bronxville Woolworth store was manufactured in McNeil's Puerto Rico facility on July 16, 1985. It was shipped as part of a lot received in Montgomeryville on September 5 and 6 and from there it was shipped to the Woolworth distribution center on September 6.

Our records show that these bottles were never in the same manufacturing facility or same distribution center at the same time.

To date, over one million capsules have been examined by the FDA and our laboratories. With the exception of the Woolworth bottle, no additional tainted capsules have been discovered. This reinforces our belief that the tamperings did not occur in our facilities. For this to have occurred, the two bottles, manufactured in different locations at different times traveling in different distribution patterns to different retail outlets, would have had to complete the process at virtually the same time only one and one-half blocks apart.

Based on this we do not believe that the tampering could have occurred in our facilities, but until the criminal responsible is found, we will not have proven where it did occur.

TAMPER RESISTANT PACKAGING

After the tamperings in the Chicago area in the Fall of 1982, the over-the-counter medications and the packaging industries examined a broad range of technologies designed to protect the consumer against product tamperings. Our company conducted an exhaustive review of virtually every viable technology. Ultimately, we selected for TYLENOL* capsules a triple safety sealed system that consists of glued flaps on the outer box, a tight printed plastic seal over the cap and neck of the bottle and a strong foil seal over the mouth of the bottle.

Our decision to reintroduce capsules was based on marketing research done during that time. This research indicated that the capsules remained the dosage form of choice for many consumers. Many felt it was easier to swallow and some felt that it provided more potent pain relief. While there is no basis in fact for the latter perception -- tablets, caplets and capsules are all equally effective -- it is not an irrelevant consideration. To the extent that some people think a pain reliever may be more powerful, a better result can often be achieved. This is due to a placebo effect but is nonetheless beneficial to the consumer.

Given these findings and our confidence in the new triple-seal packaging system, we made the decision to reintroduce TYLENOL* Extra-Strength pain relievers in capsule form.

WITHDRAWAL FROM DIRECT TO CONSUMER CAPSULE BUSINESS

Clearly circumstances are different today. As I have already indicated, in light of the Westchester events we no longer believe that we can provide an adequate level of assurance of the safety of hollow capsule products sold direct to consumers. For this reason, we made the decision to go out of that business. We will encourage consumers to use either the solid tablets or caplets. The caplet is especially well-suited to serve the needs of capsule users. It is oval shaped like a capsule, 35% smaller and coated to facilitate swallowing. It is also hard like a tablet and thus far more difficult to violate without leaving clearly visible signs. We developed this dosage form as an alternative to the capsule. Since its introduction in 1984, it has become the analgesic dosage form of choice for many consumers.

CONCLUSION

Mr. Chairman, during both the Chicago and Westchester tampering incidents, I have been deeply impressed by the commitment and performance of government agencies, especially the FDA and the FBI. I cannot imagine how any organizations could have been more professional, more energetic or more rational in exercising their responsibilities to the American public.

In addition, the media performed an invaluable role in telling the public what they needed to know in order to provide for their protection. This was accomplished swiftly and -- in the overwhelming majority of instances -- accurately. Our polls show that within the first week following the Westchester incident, 96% of consumers in America were aware of the problem. As was the case in Chicago, this is an example of how the media performs an invaluable service when the public safety is at issue.

The wide availability of self-medications through the open market in the United States is an important part of our unique health care delivery system. We must work together to maintain the advantages of this system. For industry and government, this means doing what is appropriate to provide for the safety of consumer produts. At the same time, we must assure the freedom to take full advantage of an open marketplace -- not the least of which is enlightened product selection at a reasonable cost. For the consumer, this means education and awareness. As has often been noted, no system yet designed can guarantee freedom from product tampering; careful consumers must be the most important element in providing for their own safety.

Thank you. That concludes my statement.

*Registered Trademark

The CHAIRMAN. Let me just ask a couple of questions before I turn you over to our other Senators here.

You have indicated some of the steps you have taken to resolve these problems. Can you just list any steps you have taken to assure the public that these situations are not originating within your own manufacturing facility or are the work of disgruntled employees, or something like that?

I think you have alluded to that, but I don't know that you have given us any specifics.

Mr. CLARE. Well, Mr. Chairman, we have been working very closely with the FBI in terms of providing them access to information on any potential disgruntled ex-employees, disgruntled employees; any information that could give them a lead toward identifying the potential of it being an emoloyee of ours or an ex-employee of ours.

What I have tried to describe, however, is that even if it was an employee within the system, the difficulty of their having knowledge of this random distribution and how they could end up with two separate packages from two lot numbers, two different locations——

The CHAIRMAN. I think you make a pretty good case; but are you continuing to work on that?

Mr. CLARE. Yes. We are continuing to work with the FBI.

The CHAIRMAN. I understand that Johnson & Johnson evaluated capsules other than the type used in Tylenol. Were some of those capsules not more safe or more resistant to tampering, and maybe even completely tamperproof; that you know of?

Mr. CLARE. We have evaluated, I believe, 11 different systems at the present time for capsule treatment. All of them have certain inherent design opportunities that do not permit us to say they are tamperproof.

Each of them offers some advantages and some drawbacks. We have clearly continued our investigation since 1982 on the potential of improving the dosage form, and that is why we came out with the caplet, the solid form, to essentially try and move the consumer towards a more protected product.

The CHAIRMAN. I have other questions that I will submit in writing.

[Responses of Mr. Clare to questions submitted by Senators Hatch and Grassley follow:]

Johnson & Johnson

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933-

April 3, 1986

Mr. James W. Powell
Editor
Senate Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Powell:

I am enclosing a copy of the transcript of Mr. Clare's comments regarding the Westchester County tamperings before the Senate Committee on Labor and Human Resources on February 28, 1986. The transcript has been marked to indicate a few minor corrections.

In addition, I am pleased to provide, on Mr. Clare's behalf, the following responses to the requests from Senators Hatch and Grassley for additional information:

A. Responses to Questions from Senator Hatch

1. Do you believe that all caplets are more resistant to tampering than capsules, even some of the newer types?

   Answer: Yes, solid dosage forms are inherently more difficult to tamper with than hollow capsule forms. Further, tampering which might occur with solid forms may be more easily detectable.

2. What efforts have been made since 1982 to improve tamper-resistant packaging?

   Answer: Since 1982, when our triple-sealed package for capsules was introduced, Johnson & Johnson has evaluated hundreds of ideas for tamper-resistant packaging. These have included technologies in a number of different areas including, for example, at least 11 different kinds of capsule sealing systems.

3. You and I both agree that our number one goal must be the health and safety of the American consumer. What

in your opinion should industry do to help us achieve this goal?

Answer: Our experience has not led us to conclude that there are any further steps that industry can or should take at this time, but this is an area that certainly warrants continued evaluation.

4. Is any federal legislative or FDA regulatory initiative necessary in this regard?

Answer: The cooperative effort of industry and government in 1982, which resulted in prompt adoption of tamper-evident packaging regulations and implementation of tamper-evident packaging, has provided the public with an additional level of protection. We do not believe that any further federal legislative or regulatory initiative is necessary. The FDA appears to have all of the authority it needs to handle this kind of problem. I would like to note, however, our concern that the FDA's effectiveness in other areas, such as new product approval, seems likely to diminish significantly if resources available to the agency are reduced as a result of budget cutting.

5. You state in your testimony that "no system yet designed can guarantee freedom from product tampering" and that "careful consumers must be the most important element in providing for their own safety." What specific steps can consumers take to ensure their safety from tampering?

Answer: Consumers should carefully check the entire package of any over-the-counter medicine or other consumable consumer product before opening the package. That means checking not only the tamper-evident features, such as seals, but also the rest of the package. Once the package is opened, the product itself should be scrutinized for anything unusual, including discoloration, disintegration or malodor.

B. Responses to Questions from Senator Grassley

1. You said you were shifting to exclusive use of caplets in place of capsules. Is it possible to tamper with

caplets also? And could you tell us a little more about the greater degree of safety one might achieve through use of caplets instead of capsules?

Answer: Yes, any form of medicine can be tampered with. We believe, however, that solid dosage forms are inherently more difficult to tamper with than the hollow capsule form, and that tampering may be easier to conceal with the hollow dosage form.

2. Your company has decided to stop producing capsule medications, if I understood your testimony correctly. Some of the other witnesses are going to state that no type of product should be singled out and banned. Does your decision imply that your company would recommend ceasing general use of capsules?

   Answer: No, the action that we took was based on our own circumstances. We reached the conclusion that our capsules, having been identified with this kind of tragedy, not once but twice, were more likely to be the target of the same kind of act in the future. Others will have to make their own judgments.

3. You said that you will no longer sell capsules directly to the consumer. What do you mean here? To whom will you continue to sell capsules.

   Answer: We will continue to make products available in capsule form to pharmacists and health care institutions. These are generally prescription products, access to which is controlled by a pharmacist.

4. Some survey research, as one of our witnesses will tell us today, shows that consumer concern seemed to drop off some time after the 1982 poisoning episode.

   Do your over-the-counter packages now contain conspicuous warnings about product tampering which would keep before the consumer the possibility that a package might have been tampered with?

   Answer: Yes. For example, the TYLENOLç caplet package carries the following warning in bold print:

"Warning: Do not use if carton is opened or printed foil seal is broken."

5. What kind of employee screening do you do of employees who have direct access to the manufacture of your product?

   Answer: We check the references and prior work or school history of each employee.

6. Just one question on what we know about the person or persons who tampered with your product earlier this month. How expert would you say this person is, from the evidence available to you, about the production and distribution process and about the product itself?

   Answer: It does not appear that the tamperer had to be expert in our production or distribution process, or about the product. All of the evidence suggests that the tampering occurred in Westchester County after the product was through the manufacturing and distribution process.

   The tamperer was very sophisticated and knowledgeable about how to enter and then reseal the package in a way that would not be readily apparent to the observant consumer. That kind of expertise could probably be developed through the trial-and-error method after several attempts.

7. How about the availability of cyanide? Is that something that is relatively easy to get in the form that was used to tamper with the capsules in Westchester?

   Answer: Our understanding is that cyanide in general and the kind used in Westchester in particular is available from a wide variety of sources in a relatively unrestricted way.

8. And I guess that followup: Is enough being done in the way of labeling directed to this possibility.

   Answer: Yes, labeling directing consumers to the tamper-evident features of their products seems sufficient.

Please feel free to contact me directly if there are further questions concerning this matter.

Sincerely,

Bertram J. Levine
Vice President,
Federal Relations

mjb

The **Chairman**. Let me just ask one other question before I turn to Senator Kennedy.

I personally believe that Johnson & Johnson has demonstrated, in these incidents, a really outstanding corporate ethic and responsibility.

Mr. **Clare**. Thank you, sir.

The **Chairman**. I think you have done just about everything you knew how to do. Can you tell us how these principles originated and how you pass them on to new managers within your company?

Mr. **Clare**. Well, they were really initiated in a simple statement that was written by Gen. Robert Wood Johnson in 1944, I believe, called "The Credo." It identified our first responsibility as being to the consumers of our products all over the world.

The fourth responsibility was to the stockholders; and it was put in that appropriate order. Intervening were our responsibilities to our employees and to our communities.

Our thesis is that not only do we have a moral and ethical responsibility to provide, appropriately, product to our consumers, it is good business in the long term to have a relationship with the consumers that they trust us; and we have continued to challenge that statement. We use it for all of our new managers coming into the company as a basis for identifying whether or not they believe it.

We continue to feel that it stands us in very good stead. We are benefited by having it.

The Tylenol incident in 1982 and this one have really cast it in stone as far as the corporation is concerned.

The **Chairman**. Well, thank you so much, Mr. Clare.

Mr. **Clare**. Thank you.

The **Chairman**. I will turn to Senator Kennedy at this time.

Senator **Kennedy**. I, too, want to join in welcoming you. Thank you for the cooperation that the firm of Johnson & Johnson has had with the committee in the development of these hearings.

Could you outline a little bit what internal measures you took after the first deaths of 1982: what steps were taken within the Johnson & Johnson corporation?

Mr. **Clare**. Are you talking, Senator, in terms of the steps of publicity or the steps——

Senator **Kennedy**. No. I am talking internally, within the corporation.

Mr. **Clare**. Well, internally our main emphasis in 1982 was to attempt to identify whether capsules were desired, needed and proper; second, how to enhance the tamperproof nature, if at all possible. But we came to the realization all we could do was make it tamper-resistant, not tamperproof.

Third, we substantially enhanced our attention to various technologies leading towards even further improvement in the dosage forms and the packaging; and that has been ongoing ever since. On top of it, of course, we also reviewed our own security, our own product control, and enhanced the quality control of our process.

Is that addressing the issues you were——

Senator **Kennedy**. Well, that is certainly helpful.

Some time after the 1982, did you not purchase a sonic sealing machine?

Mr. CLARE. Yes; we did, Senator.

Senator KENNEDY. Why did you do that?

Mr. CLARE. We purchased a number of units in an attempt to identify the viability of improved processes for sealing the capsules as an additional measure. The sonic-sealing unit that was purchased was purchased and tested extensively.

I think we have produced, through that machine, well over 10 million capsules so far.

Senator KENNEDY. You are using that at the present time?

Mr. CLARE. We are using it purely in an experimental mode.

Senator KENNEDY. It is not used in terms of the production?

Mr. CLARE. No; it is not.

Senator KENNEDY. Did you draw any conclusions from the use of that in the experimental mode? Was it more safe or less safe than the procedures that you were using?

Mr. CLARE. I think the conclusion essentially, Senator, was that it was not a situation of black and white. It improved in some characteristics. It did not meet our standards in terms of failure rate of the seal and the potential for dusting in the package, leakers.

We had concern, recognizing the potential, that dusting in the package would be of concern to the consumer.

Senator KENNEDY. Did you draw any conclusion with regards to the tampering aspect of the package? Did this provide greater——

Mr. CLARE. Of the package or the individual sealed capsules?

Senator KENNEDY. The sealed capsules, first of all.

Mr. CLARE. Yes; we did, Senator. In terms of the package, the sealed capsule, we found that the sealing rate in our tests, after shipping, after delivery, was not up to a standard which we felt we had to meet. It was significant, but still not up to the standard we felt we had to meet.

Senator KENNEDY. Well, the standard includes other, I suppose, criteria, other than safety?

Mr. CLARE. No. I think that the basic issue was——

Senator KENNEDY. You are talking about the safety standard here?

Mr. CLARE. Yes, safety standard and the perception of safety to the consumer.

Senator KENNEDY. Well, I think they are both important.

Do you know if other manufacturers use that solution?

Mr. CLARE. I believe so, Senator. I heard the manufacturer of the sonic sealing machine is scheduled to testify. Undoubtedly he can give you more specific information.

Senator KENNEDY. Have you, just in terms of your own communication with those kinds of manufacturers, drawn any conclusion from the review of the material, perhaps that has been developed even by those corporations, whether they believe it to be safer and more secure?

Mr. CLARE. They appropriately point out it may be safer than an unsealed capsule. Our problem, as you well recognize, Senator, is we are dealing with Tylenol, the specific brand.

Having been struck by lightning once in 1982 and now the second time in 1986, the degree to which we have to provide assurance is perhaps greater than other manufacturers may be faced with.

Senator KENNEDY. Should the consumers assume that the tablets also are not tamperproof?

Mr. CLARE. Absolutely not, Senator.

Senator KENNEDY. Do you want to elaborate, briefly?

Mr. CLARE. Any package that we can identify a determined intelligent criminal can invade. All we can say is that in tablets and, even more specifically, in the caplet which is coated, it is much more difficult to accomplish than in a hollow capsule.

Senator KENNEDY. In another area—because our time is moving—the FBI has now announced that previously undetected signs of tampering have now been discovered and that the poisoning occurred independent of the manufacturing process.

Mr. CLARE. We were very relieved to have them identify that.

Senator KENNEDY. That was a release that was out about a week ago; I think it was on the 26th.

Do you have any idea how they reached that conclusion?

Mr. CLARE. I'm sorry, I do not, Senator. We have been working with them, but they have not obviously shared that with us.

Senator KENNEDY. Is it the position of the company, then, based upon that report—there was a different report earlier which we will get into with regards to the FBI—the executives and those in charge of the safety and security program that tampering could not have occurred during the manufacturing and distribution process?

Mr. CLARE. It has been our belief from the first time that we completed the evaluation that it was unlikely because of the random distribution nature of the product. We have obviously continued to review our own security, our own internal controls.

Senator KENNEDY. Then your answer is yes, from the FBI report you believe that that supports your earlier——

Mr. CLARE. Yes. I'm sorry if I got off——

Senator KENNEDY. Fine. Just a final question.

At the start of the hearing, we should have asked the question: How safe should the consumer, the average person—perhaps watching this hearing—who goes to the local drug store or the super market and buys over-the-counter products such as produced by Johnson & Johnson and others, as well, that all of us are familiar with, feel today when they go to that store and purchase pain relievers?

Mr. CLARE. Senator, since the establishment of the safety-seal program for the industry back in 1982, we have produced what I guess is approaching a billion packages under the safety-seal program for our products; and the industry undoubtedly has produced 1 or 2 more billion packages.

To have found, in 3½ years, two packages invaded out of several billion is, I think, a degree of assurance that is being provided by the system that currently exists. That does not mean it is perfect, but it is an order of magnitude of perfection that is pretty close.

Senator KENNEDY. Well, would you say it is somewhat safe, very safe, extremely safe?

Mr. CLARE. I think the system, itself, is extremely safe; but not perfect.

Senator KENNEDY. Thank you.

The CHAIRMAN. Senator Stafford?

Senator STAFFORD. Thank you, Mr. Chairman.

Mr. Clare, in the discussion of tablets and caplets, and the fact that even they are not tamperproof I understand from your testimony, could you suggest to the committee what sort of evidence the consumer might look for if tampering with a caplet, for example, had occurred?

Mr. CLARE. The most common, Senator, is discoloration; of course, any obvious physical disintegration of the tablet or caplet, not just a chipping but a major disintegration. Any disintegration or discoloration would be cause for concern to a consumer.

Senator STAFFORD. Do you continue to put caplets, for example, in as tamperproof a package as you can?

Mr. CLARE. We are reviewing that again, Senator, and examining whether the opportunity is there to enhance, in the solid dosage form, our tamper-resistant packaging. In the original plan when we released the capsules back in 1982, we had put them in a triple seal. In the solid dosage form, we had a double seal perceiving that the solid form, itself, became the third barrier helping in identification of tampering.

Our current review is towards what can we do to substantially enhance the protection of the solid dosage form.

Senator STAFFORD. I suppose the more work you go to to make the packaging tamperproof, the more expensive the process becomes for you and you have to pass that on to the consumer.

Mr. CLARE. I think equally important, Senator, is the more difficulty that some of the consumers have in gaining access to the product. We are constantly fighting the balance between making it impossible to get into and making it possible to get into for the consumer.

Senator STAFFORD. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Metzenbaum.

Senator METZENBAUM. Mr. Clare, first I would say that I would agree that Johnson & Johnson conducted itself in a responsible corporate manner. To take the dramatic action that you did, totally abandoning the capsule field took some high degree of corporate responsibility. It impressed this Senator very favorably.

I am curious to know about these three seals.

As I understand, the box is sealed, the bottle is sealed, the capsule is sealed.

Mr. CLARE. No, not the capsule, Senator; the top——

Senator METZENBAUM. Well, the capsule is the capsule.

Mr. CLARE. The top of the bottle was sealed.

Senator METZENBAUM. The top of the bottle was sealed.

Is the bottle opened and then resealed? Is that what you found in these instances?

Mr. CLARE. I think that the better people to answer that may be the FBI, but it is our belief that the three barriers to entry were violated without difficulty by a very sophisticated individual. We know how to do it.

What has baffled us all along, though, was the difficulty in doing it without leaving some traces that it had occurred. What I gather from the FBI statement, which I read along with the rest of you, the FBI, using very sophisticated technologies, has identified some trail which identified that it was tampered with.

Senator METZENBAUM. Was there any evidence in the stores in which these products were sold that other bottles had been tampered with?

Mr. CLARE. Not to our knowledge, Senator. We have clearly identified the two separate stores, the two separate bottles one in each store, but no indication that I am aware of of any further bottles in either store or any of the other locations in that area.

Senator METZENBAUM. Is there any reason to believe that this tampering is related to that which occurred in Chicago?

Mr. CLARE. There are those who would theorize that, Senator. I find it difficult.

We have received no indication. The cyanide was different; 3½ years apart was different.

Senator METZENBAUM. Different kind of cyanide, you are saying?

Mr. CLARE. Yes. The cyanide was different between Chicago and New York. The fact that it was a local event within a block and a half leads us to believe that they are two separate unrelated events.

Recognize, also, Senator, in 1982 extortion attempts were made against Johnson & Johnson; the most prominent extortionist ended up in jail. There were several extortion attempts.

This time there has been no extortion attempt against us. There was a letter apparently attempting to extort the police in Bronxville, but not Johnson & Johnson.

Senator METZENBAUM. I'm sorry, I did not get that.

Mr. CLARE. A letter in Bronxville was found which threatened extortion against the local police, that he was the second Tylenol killer, but no attempt has been made to involve us in an extortion attempt.

Senator METZENBAUM. Without asking you to identify any persons or groups, do you have any particular suspicion as to why or who or how this came about?

Mr. CLARE. Senator, we have been so busy in attempting to deal with our problems that we have made it a pact among ourselves we are not going to waste time trying to play detective; and we all want to do it. Each of us may have a particular concept.

But we are not spending much time on addressing who did it.

Senator METZENBAUM. An analyst at E.F. Hutton, just this past week, says that you went overboard last week in your actions. Do you care to comment on that?

Mr. CLARE. Well, I would like to know in what context he thought we went overboard. If he says we went overboard in terms of protecting the consumer, I disagree with him.

If he says we went overboard in terms of acting quickly, I disagree with him.

Senator METZENBAUM. I think I do, too.

Mr. CLARE. Thank you.

Senator METZENBAUM. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Thurmond.

Senator THURMOND. Thank you very much.

Mr. Clare, I want to congratulate your company for the fine spirit of cooperation that you have shown in this matter.

Mr. CLARE. Thank you, sir.

Senator THURMOND. Also, in offering to the public to replace the capsules with caplets or tablets. What do you call this?

Mr. CLARE. Caplets, Senator.

Senator THURMOND. Caplets.

I want to ask you this. A great many people have wondered, in the capsules, was the capsule opened, the cyanide poured in there or was some of the contents of the capsule removed and replaced with cyanide?

Mr. CLARE. Senator, the capsules were examined specifically by the FDA. I am sure they can give you a more accurate description.

But my understanding is that what happened is they took the capsules apart, dumped the entire Tylenol contents out, and then replaced the entire contents with cyanide and reassembled the capsule.

Senator THURMOND. And the cyanide was the same color as the contents of the capsule so that a consumer could not tell the difference?

Mr. CLARE. I believe in terms of the original time at which it was done, it would probably have been a white material; but at the time of the investigation of the remainder of the capsules, it had turned brown by then.

Senator THURMOND. I was just thinking if the cyanide would be the exact color, would it be a darker color, or would it be a streaked color so the consumer could tell.

Mr. CLARE. Well, I think you can get a more scientifically accurate answer to that from the FDA, but it is my understanding, Senator, that the issue—it discolors and the potassium cyanide that was in the Bronxville area had turned brownish color, and you could see it through the white part of the capsules.

Senator THURMOND. Now, with regard to the caplets, would it be possible for someone who wanted to tamper, as was done, to remove part of the caplet and replace that with cyanide, or would that be the same color?

Mr. CLARE. Well, Senator, we know that any package, including a solid-dosage form of tablet or caplet, can be invaded. It can be tampered with.

I am not talking about counterfeiting. I am talking about taking the product and invading and tampering with it.

We know it is much more difficult to do with the solid-dosage forms than a hollow form. We know that the end result of tampering by a very sophisticated criminal could be very difficult for a consumer to identify.

We perceive the individual who did this in Bronxville, or where the product ended up in Bronxville, is a very sophisticated individual, very smart individual.

You are asking me to demonstrate how to do it and I would not want to do that if we could avoid it.

Senator THURMOND. Do you feel the public is safe today to use these caplets, and could they determine if there was cyanide or some impurity in them?

Mr. **Clare**. Senator, I think the public has the maximum degree of assurance of safety that any product can deliver in using the caplet. That is not absolute perfection.

There is no absolute protection as we know it today.

Senator **Thurmond**. In other words, with these caplets if they had been tampered with you think a consumer would be able to identify that when they opened the package.

Mr. **Clare**. Well, it depends upon how long after the tampering. There is a gradual deterioration of the caplet if it has been tampered with. There is a gradual discoloration of the caplet if it has been tampered with.

Senator **Thurmond**. So many people use Tylenol today, I am just wondering if you feel that they would be safe in continuing to use these caplets like they did use, previously, the capsules.

Mr. **Clare**. Yes, sir, I do. Not only is the Senator who said he gets sick occasionally, but I am a Tylenol user. I feel very comfortable with the caplet.

Senator **Thurmond**. Could you tell us what was ever discovered as to the motive in 1982 in what happened then? Was that someone who lost his job with the company or someone who was mad with the company, or someone who was just sick mentally and wanted to harm somebody to see the results and so forth?

How do you account for that then?

Mr. **Clare**. Senator, since the criminal or criminals in 1982 have not yet been apprehended, it is very difficult to identify what their reason was. We do know that an extortion attempt was made by a very sophisticated individual. He currently is in jail.

Whether there is adequate proof to connect him to the individual case, apparently there is not.

I don't have any proof as to who did it in 1982, why they did it in 1982; but I do know that, in this event, we have not been extorted and there have been no attempts to extort us in the interval since 1982.

Senator **Thurmond**. So you don't know whether there was a similar motive then compared with the recent event.

Mr. **Clare**. If you will accept that the motive was extortion in 1982 and the lack of extortion being evident in 1986, then it gives you reason to believe there are two different reasons for the individuals to have done it.

In 1982, we saw it as essentially an extortion attempt; in 1986, no attempt at extortion, only two bottles, a different pattern, different cyanide. We think they are two unrelated events.

Senator **Thurmond**. Would it be helpful if the public generally would keep their eyes and ears open in connection not only with Tylenol, but any other medicine in which there might be some evidence of tampering and report that to the Food and Drug Administration?

Mr. **Clare**. Senator, I would urge that the public keep their eyes open not only in medicines, but in foods and all of the packages that they have easy access to. The ultimate protection is provided by an intelligent consumer and provided by his or her self-inspection of what they are purchasing.

Senator Thurmond. In other words, a consumer today should be very careful of what they are purchasing because they don't know what foreign element could have been inserted there.

Mr. CLARE. That is right, Senator.

Senator THURMOND. Now, recently they have found some glass in Gerber's baby food. Of course, that is a terrible thing, too. Does that indicate to you that maybe there is another individual that has the idea of hurting people or causing people to be frightened from buying food in general, and that the public has to be on guard in every way possible to protect themselves?

Mr. CLARE. Well, Senator, I am not competent to judge the baby food/glass incidents. I am not close enough to it.

But my own perception from having raised four children and used baby foods all along is that inherent in the package of a glass jar, which is designed to make it convenient for the consumer to keep and cook the material, is the potential of shipping or something causing a cracking of pieces of glass around the rim.

Whether that is the case in this instance, I just don't know, Senator; but my impression is that the incidence rate is so low that it sounds to me rather than being a concerted effort by somebody that it is just random breaking.

I really am not competent to make that judgment.

Senator THURMOND. I presume you would agree then, that the Tylenol incident and the baby food incident should cause consumers—and it is chiefly the women, I guess, who buy these items for the family—to be very careful and examine specifically every item they buy that could have been tampered with as other people could be injured if there has been any tampering with any of these items.

Mr. CLARE. I could not have said it better, Senator.

Senator THURMOND. Thank you very much.

The CHAIRMAN. Thank you.

Senator Kennedy and then Senator Metzenbaum. They each have a question.

Senator KENNEDY. On February 18, the FBI announced that their tests showed that there was no evidence of tampering, and the day before Johnson & Johnson announced that they were going to withdraw the capsule products from the market.

Were you aware or was Johnson & Johnson aware of the FBI results?

Mr. CLARE. No. We were very pleasantly surprised and pleased with the announcement. Surprised is not the right word. I guess we were mostly——

Senator KENNEDY. I am speaking of the earlier announcement on the 18th.

Mr. CLARE. 18th announcement?

Senator KENNEDY. That's when they indicated that there was no tampering.

Mr. CLARE. Oh. I'm sorry.

Senator KENNEDY. So that would I expect, at least in their findings, shift it back toward the problems of the company, and then the next day there was the announcement of Johnson & Johnson that they were not going to use capsules anymore.

I am just interested to what extent you knew what the conclusions were of the FBI report.

Mr. Clare. We were aware, through contacts with the FBI and our own packaging people had been in contact with their experts to try to identify how the capsules could be invaded.

That announcement and our decision were unrelated events. Our decision was based on essentially our——

Senator Kennedy. Your own findings. Is that right?

Mr. Clare. That's correct.

Senator Kennedy. The question was, did you know that the FBI had reached that conclusion prior to the time that you made your announcement?

Mr. Clare. Yes; I think, Senator, they had announced that there was no evidence of tampering even before February 18, if I have my script right. So we knew that was their announced position before that.

Senator Kennedy. Thank you.

The **Chairman.** Senator Metzenbaum.

Senator Metzenbaum. Thank you.

Mr. Clare, you answered one question—I'm not sure whose it was, it may have been Senator Thurmond's—that in this case you have not been extorted almost leaving the implication that in other incidents you have been extorted.

Mr. Clare. I was referring, Senator, to 1982 where we got, as I remember, five extortion notes.

Senator Metzenbaum. Is that quite customary for pharmaceutical companies to receive extortion notes or extortion demands?

Mr. Clare. I don't believe so. That's the only instance that I can remember in my almost 40 years with the company of our getting them and it was all centered on Tylenol.

It was obvious that some of them were so false as to have included in an extortion note their return address, which helped identify them pretty quickly.

I felt, at that time, it was purely the tremendous publicity associated with the program: That opportunistic extorters were trying to get at us.

Senator Metzenbaum. You are talking about the ability to tamper with the capsule or the caplet.

Mr. Clare. Yes, sir.

Senator Metzenbaum. What about the ability to substitute total caplets that look like Tylenol or any other products that are involved?

Mr. Clare. Well, Senator, if it is a caplet imprinted on the side in a particular color and shape—you see imprinted here, "Tylenol, 500 mg." They would have to get, in addition to materials, our stamps, our materials and do the coating and printing in the exact same way we do it.

I don't think that that's a reasonable expectation. On the tablets, they are uniquely pressed with a mark in each tablet that makes it very difficult unless somebody gets our particular press.

Senator Metzenbaum. I guess really the bottom line is that, do you suppose a forger could do that imprinting: That no matter how many steps you take to confront the problem there probably always is another way, if you are determined and have enough resources and funds, that you can achieve your objective.

I guess even as you and Senator Thurmond have stated and you have repeated a couple of times and it is in your remarks, the consumer has to be, in the last analysis, very aware. I just don't know if that is possible.

I guess that it is one of the risks that we take in a society of this kind, and you do the best you can. But I don't know that you can ever be totally fail-safe.

Mr. CLARE. I don't know that there is such a thing as a risk-free society in a number of dimensions. Whether it is forgery of Tylenol or currency, it is possible to do; but highly unlikely in our opinion.

Senator METZENBAUM. Thank you very much.

The CHAIRMAN. Thank you, Senator.

I want to thank you, Mr. Clare, for being with us. We appreciate the problems that you have and we appreciate the way that your corporate management has addressed them.

So we appreciate having you with us.

Mr. CLARE. Thank you very much, Mr. Chairman.

The CHAIRMAN. We will now turn to our second panel: Dr. Frank E. Young, Commissioner of the Food and Drug Administration; Mr. Nicholas V. O'Hara, Chief of the General Crimes Section of the Criminal Investigative Division of the Federal Bureau of Investigation; and Ms. Carol G. Dawson, the Acting Chairman of the Consumer Product Safety Commission.

We want to welcome all three of you to the committee. We are very happy to have you here and we look forward to hearing your testimony.

We will turn to you, Dr. Young, first.

STATEMENTS OF DR. FRANK E. YOUNG, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMEMT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JOHN NORRIS, DEPUTY COMMISSIONER AND DAN MICHAELS, DIRECTOR, OFFICE OF COMPLIANCE; NICHOLAS V. O'HARA, CHIEF, GENERAL CRIMES SECTION, CRIMINAL INVESTIGATIVE DIVISION, FEDERAL BUREAU OF INVESTIGATION; AND CAROL G. DAWSON, ACTING CHAIRMAN, U.S. CONSUMER PRODUCT SAFETY COMMISSION, ACCOMPANIED BY MICHAEL GIDDING, COMMUNICATION STAFF

Dr. YOUNG. Thank you very much, Mr. Chairman. I am particularly pleased to be able to participate in this hearing and I thank you and the other Senators for calling this to highlight a focus on consumer protection and ways in which we can deal with this most important tragedy.

Because of the shortness of time, sir, I will abstract my testimony and submit it for the record if that is acceptable.

The CHAIRMAN. Thank you.

Dr. YOUNG. I am accompanied by Mr. John Norris and also with me, as a resource person, is Mr. Dan Michaels who is Director of our Office of Compliance so that we can provide any further answers for you.

The CHAIRMAN. You bet.

Dr. YOUNG. We are here today to discuss the actions that have been taken by FDA as national attention has once again focused on a cyanide poisoning death relating to the ingestion of Extra-Strength Tylenol capsules. Our actions, during the week and the days following February 10, were prompt and responsible.

From the very first moment of the crisis, our first and constant concern has been protection of public health. We took a number of steps immediately after these events.

First, we, too, as was mentioned by Johnson & Johnson, were notified early by the authorities in Bronxville, NY, and learned that the bottle did contain capsules containing cyanide. Following this, we used our field investigators to collect samples from the remaining stores in the Greater Yonkers area and we analyzed them for cyanide.

The so-called second bottle was removed from stocks at a retail store by an FDA investigator. Analyses of these two bottles showed that the cyanide that was present was potassium cyanide; the cyanide used in the Greater Yonkers area was chemically very distinct from the cyanide that was used in the earlier Tylenol poisoning in Chicago.

We have looked at, in excess, now, of 1,770,000 capsules not only from the Greater Yonkers area, but of other lots similar to those that were involved—the ADF-916 and the AHA-090—and have found no evidence of tampering and no evidence of cyanide in any of these capsules.

Since that time, also, as with your hearing, I have had a number of informal meetings, from which I will submit the minutes for the record and go into more detail, with consumer and professional groups, State and local health authorities, and trade associations to understand more fully some of the complexities involved in these issues.

[Information supplied follows:]

MEMORANDUM OF MEETING

ATTENDEES

FDA

Dr. Young
Mr. Norris
Mr. Grant
Ms. Kulakow
Ms. Gipple
Dr. Meyer
Mr. Levitt
Mr. Schwemer
Mr. Michels
Dr. Nightingale

IOM

Dr. Thier

Consumer Representatives

Ms. Judy Brown, AARP
Mr. Robert Humphreys, AF
Ms. Mary Ellen Fise, CFA
Ms. Nancy Bowers, FOH
Mr. Bill Bogan, COSSMHO
Ms. Linda Golodner, NCL
Ms. Margie Word, NCNW
Mr. Chris Papps, NCSC
Ms. Susan Abbott, NCA
Ms. Suzanne Bergeron, NUL
Ms. Diane Barzman, PVFHP
Mr. William Schultz, PCLG
Ms. Nancy Olins, RPS
Ms. Juanita Yates, USOCA

SUBJECT: Follow-up to OTC Product Tampering

DATE: February 21, 1986

On February 21 FDA Commissioner Frank Young, M.D., Ph.D., met with a group of consumer leaders (listed above) in order to brief them on the recent Tylenol tampering and to get their views on actions, if any, that the Agency might consider taking as a result of the tampering incident.

The following points are illustrative of those raised at the meeting:

- Since Agency resources are limited and mandatory action would not be effective in eliminating future tamperings, FDA should not expend efforts to develop new regulations. Instead, public education should be the way to alert consumers on how to protect themselves.
- An abbreviated brochure similar to "Tips Against Tampering" (developed by USP) should be made available to the public.
- Information for the general public should also take such forms as:
    - PSA announcements: they would be particularly useful at this time since sensitivity to tamperings is high and will be again if the criminal is apprehended.

MEMORANDUM OF MEETING

ATTENDEES

FDA

Dr. Young
Mr. Norris
Dr. Nightingale
Dr. Meyer
Mr. Levitt
Mr. Schwemer
Mr. Grant
Dr. Holohan
Mr. Michels

Health Professional Representatives

Dr. K. Lampe, AMA
Ms. R. Sweeney, AAFP
Ms. D. Prout, ACP
Mr. W. Heller, USP
Mr. J. Valentino, USP
Dr. J. Schlegel, APhA
Dr. G. Crooks, APhA
Dr. S. Thier, IOM

SUBJECT: Follow-up to OTC Product Tampering

DATE: February 21, 1986

This meeting was requested by Dr. Young to brief health professional representatives on the status of the OTC product tampering investigation and to solicit views on what the public reaction has been and what remedial action, if any, would be considered appropriate. The following points are illustrative of those raised at the meeting:

1. FDA's response should be a cautious, measured response, not precipitous.

2. Tamper-resistance does not equal tamper-proof. A determined individual may be able to successfully tamper with even sophisticated packaging schemes.

3. Responding to a criminal act is different from responding to the typical public health problem and requires a different approach.

4. The emphasis on capsule dosage form per se and safety considerations may be inappropriate. No organization expressed a desire to have capsules removed from the market.

5. Patient awareness in examining medications should be increased. USP will update a pamphlet on this subject first prepared in 1982. (The 1982 version was distributed to meeting participants.)

The Commissioner thanked everyone for their thoughtful comments and for taking the time to come in.

Stuart L. Nightingale
Stuart L. Nightingale, M.D.

MEMORANDUM OF MEETING

ATTENDEES

FDA

Dr. Young
Mr. Norris
Mr. Levitt
Mr. Schwemer
Mr. Michels
Dr. Nightingale

Drug Trade Associations

Ms. M. Badington, APhA
Ms. G. Crooks, APhA
Ms. L. Harteker, ASHP
Mr. N. Mulcahy, PMA
Dr. J. Jennings, PMA
Mr. J. Walden, PA
Mr. D. Miller, NARD
Mr. B. Tindall, NARD
Mr. T. Kelley, NACDS
Ms. M. Millonig, NACDS
Mr. G. Schwartz, NAPM
Mr. N. Barry, NAPM

SUBJECT: Follow-up to OTC Product Tampering

DATE: February 24, 1986

This meeting was requested by Dr. Young to brief drug trade association representatives on the status of the OTC product tampering investigation and to solicit views on what the public reaction has been and what remedial action, if any, would be considered appropriate. The following points are illustrative of those raised at the meeting:

1. OTC products have an impressive safety record. Since the 1982 Chicago tamperings, only an approximate one in one billion capsules sold in the United States have been tainted.

2. It would be imprudent to ban capsules, since they have a valuable use and since all dosage forms have some degree of vulnerability.

3. The tamper-resistant packaging concept is valid, but the industry should work towards further improvements, both in packaging and in product formulation.

4. Changes in TRP should take into consideration the needs of both the handicapped and the elderly.

5. Contract manufacturers have special concerns regarding their ability to meet the needs of a broad spectrum of companies, particularly in individualizing different product lines.

6. Greater educational efforts should be focused towards both the consumer and the pharmacist.

The Commissioner thanked everyone for their thoughtful comments and for taking the time to come in.

Joseph A Levitt

Joseph A. Levitt

MEMORANDUM OF MEETING

ATTENDEES

FDA

Dr. Young
Mr. Norris
Mr. Levitt
Mr. Schwemer
Mr. Michels
Mr. Hamilton
Mr. Davis
Dr. Nightingale

Encapsulators and Packagers

Mr. E. Davis, Eli Lilly
Mr. R. Williams, Eli Lilly
Mr. A Carnaghi, Eli Lilly
Mr. D. Davies, R.P. Scherer Co.
Mr. R. Jimerson, R.P. Scherer Co.
Mr. P. VanKeuien, American Can
Mr. R. Schofield, American Can
Mr. Yakatan, Warner Lambert
Mr. C. Hoover, Warner Lambert
Mr. R. Jimerson, R.P. Scherer

SUBJECT: Follow-up to OTC Product Tampering

DATE: February 24, 1986

This meeting was requested by Dr. Young to brief industry encapsulators and packaging representatives on the status of the OTC product tampering investigation and to solicit views on what the public reaction has been and what remedial action, if any, would be considered appropriate. The following points are illustrative of those raised at the meeting:

1. Eli Lilly and Company presented a new seal that had been developed for hard shell capsules, called the "Quali-Seal."

2. Warner-Lambert Company presented a new thermal sealing technique for hard shell capsules, combined with a "supro seal" that makes it more difficult to break a capsule apart.

3. R. P. Scherer Corp. presented its technologies that focused on soft-gel capsules which are one piece and, therefore, cannot be pulled apart.

4. American Can presented its packaging technology which has been used widely for food products but, to date, only in more limited forms for drug products.

5. The manufacturers agreed that all these advances represented an additional layer of safety, but that none could be characterized as absolutely tamper-proof.

6. It was also pointed out that these technological advances had been under development for several years.

The Commissioner thanked them for their presentations and for taking the time to come in.

Joseph A Levitt

Joseph A. Levitt

MEMORANDUM OF MEETING

ATTENDEES:

FDA

Dr. F. Young
Mr. J. Norris
Mr. C. Prettyman
Mr. W. Schwemer
Dr. S. Miller
Ms. J. Marrone
Mr. D. Michels

Food Trade Associations

Mr. D. Richman, Giant Food Inc. (FMI)
Mr. G. Koch, GMA
Mr. S. Gardner, GMA
Mr. J. B. Cordaro, CRN
Mr. A. McGhee, FMI
Mr. K. Grahl, NACS
Mr. D. Eldredge, PLMA

SUBJECT: Follow-up to OTC Product Tampering

DATE: February 24, 1986

This meeting was requested by Dr. Young to brief food trade association representatives on the status of the OTC product tampering investigation and to solicit views on what the public reaction has been and what remedial action, if any, would be considered appropriate. The following points are illustrative of those raised at the meeting:

1. TRP efforts since 1982 have resulted in a decline in tampering efforts.

2. No TRP technology is tamper-proof. Yet, every effort will be made to improve TRP where possible.

3. Current evidence does not support the removal of capsule dosage forms from the OTC marketplace. Moreover, removal of capsules would possibly serve to "reward" tampers and shift efforts to another dosage form.

4. Considering the huge volume of trade in OTC capsules, the safety record is exceptionally good compared to other risks such as motor vehicles, home accidents, and other accidental deaths and injuries.

5. Efforts should be increased to educate consumers to look carefully at products for signs of tampering. Educational efforts should begin soon while public interest is still high.

6. There are many more food packages traded per year than OTC drug packages, yet product complaints are limited to very few, local occurences.

7. Labels on products should direct the consumer to be aware of the TRP techniques used on a particular product.

8. The Food Trade Associations believe it important to maintain consumer confidence in the supermarkets and local markets. Certain improvements can be made to increase store security in many instances.

9. The timing of increased consumer and employee training is critical and should occur soon.

The Commissioner thanked everyone for their thoughtful comments and for taking the time to come in.

CW Prettyman
Charles W. Prettyman

MEMORANDUM OF MEETING

Attendees

FDA

Dr. F. Young
Mr. J. Norris
Mr. C. Prettyman
Mr. H. Wilms
Mr. D. Michels

State Health Authorities

Mr. D. Work, NABP
Dr. B. Turnock, ASTHO
Mr. J. Ogun, AFDO

SUBJECT: Follow-up to OTC Product Tampering

DATE: February 26, 1986

This meeting was requested by Dr. Young to brief State and local health authorities on the status of the OTC product tampering investigation and to solocit views on what the public reaction has been and what remedial action, if any, would be considered appropriate. The following points are illustrative of those raised by the State health authorities at the meeting:

1. Efforts should be directed at assuring prompt and accurate communications between appropriate parties representing FDA and State officials during periods of serious health problems such as consumer product tampering. This effort will also help control rumors.
2. The Public should be better educated about tampering and not be fooled into believing any product or container is "tamper-proof."
3. The industry might consider establishing a rating scale for various forms of tamper resistant packaging and dosage forms.
4. The history of capsule OTC dosage forms speaks well of the safety of these products compared with other potential consumer risks.
5. Some concern was voiced that if tampering incidents increase, consumers and marketplace may force "behind the counter" sales of OTC products. However, this was not preferred by anyone present.

The Commissioner thanked everyone for their thoughtful comments and for taking the time to come in.

CW Prettyman
Charles W. Prettyman

-- Symbols and codes: Non-English speaking and illiterate populations need an alternative to written information.

- Organizations such as AARP, CFA, and others can use their newsletters, magazines or other networking capacities to notify constituencies about the signs of product tampering.

- Several upcoming events will provide opportunities to inform the public about tampering; some of these are the Poison Prevention Conference on March 16-17, National Consumers Week in April, and Older Americans Month in May.

- A simple poster with a strong, clear message is an effective means of notifying the public of ways to notice product tampering. Chain drug stores may be willing to make these materials available to the public.

- The Agency should encourage the industry to provide concise information on the outside of the packaging, advising the consumer to inspect the container for evidence of tampering before purchase.

- Education efforts might also take such forms as a toll free number by industry or a flyer mailed with Social Security checks; it may be more effective, however, to have such information included with the OTC drug products.

- The Agency should perform a cost-benefit analysis before it embarks on a public education campaign to determine if resources allocated to such an effort would be wisely spent, or whether such resources should be devoted to other important Agency priorities.

- FDA should review the effects of TRP for the elderly, especially the disabled, to determine if there is unnecessary redundancy in the packaging.

The consensus of the consumer leaders was that we do not have to ban all OTC capsules. There was also agreement among the consumers that public education and information, rather than regulation, should be the recommended route of action. Through consumer, industry and government networks, the public can learn how to recognize many signs of tampering. The group concurred, however, that although education may be somewhat effective in raising awareness, its ability to address the problem was limited; Agency resources, therefore, should be expended prudently.

The Commissioner thanked the group for their thoughtful comments.

Alexander Grant
Alexander Grant
Associate Commissioner for
Consumer Affairs

Dr. **Young**. These groups recognized that tamper-resistance does not mean tamperproof and that it is difficult, if not impossible, to prevent this type of dedicated criminal activity that appears to have occurred in New York as was evidenced by some of the questions and answers, particularly the last one that Senator Metzenbaum elicited.

I will not go into the chronology further other than to state one particular point. We were able to work very closely with the FBI, the State of New York—particularly with Dr. Axelrod's office—with the officials from Johnson & Johnson and others; and I want to particularly thank the media for the accurate, rapid and precise way in which they helped me communicate to the American people the issues that were at hand.

I think it was an excellent example of responsible and prompt media reporting.

As Johnson & Johnson mentioned, on February 17 they announced their decision to discontinue the distribution of all drug products in capsule form sold directly to the consumer; and, as they mentioned, the company offered to exchange, without charge, a new bottle of Tylenol caplets for any Tylenol capsules still in the hands of consumers.

We respect their decision in this matter, but it is important to point out that it was an independent decision on their part.

In addition to examining large numbers of Tylenol capsules, the FDA, in its responsible actions under the Anti-Tampering Act supported the FBI in the investigation of all of the McNeil Laboratory plants where Tylenol capsules are produced to determine whether poison might have been introduced into the product during the manufacturing process.

Based on the information gained from these inspections, there is no evidence to suggest that tampering took place at the point of manufacture and, therefore, that the tampering is anything other than a purely local incident. My colleagues from the FBI will provide further information on that during their statements on this panel.

Senator **Metzenbaum**. Did you say is anything other than?

Dr. **Young**. A local tampering incident, local in the region rather than in the plant, sir.

As you know, over 3 years ago FDA was faced with an unprecedented malicious tampering with nonprescription drug products that resulted in the death of seven people in the Chicago area. In the weeks that followed that tragic event, the private sector and the Government worked together in a manner and at a pace never before experienced to develop and to put in place improved packaging systems.

These were in an effort to provide, as was discussed earlier, additional safeguards for the benefit of public health. The regulations, requiring tamper-resistant packaging for certain of the over-the-counter, or OTC, products, were published approximately 5 weeks after the incident occurred.

Under this regulation, manufacturers could choose among various techniques—seals, shrink-bands, bubble or strip packs, and many other examples could be provided—that essentially highlight the fact that a barrier with a distinctive design is introduced, and that this design should be hard to duplicate.

This allowed manufacturers flexibility as to which methods of tamper-resistant packaging they would use.

It was also the intent to allow for newer methods being developed all the time to be included; and, as well, to encourage research and development of new additional methods for protection.

I will, if you wish, describe some of those methods that have been developed over this period of time and can submit that for the record.

As former Secretary Schweiker stated at that time:

> While it is virtually impossible to make any package tamperproof, it is possible to manufacture packages in such a way that tampering is much more difficult and if a product is tampered with it can be easily detected by a careful consumer.

Since that time, there has been a continuing effort on the part of industry to improve upon the existing packaging systems.

It is important to emphasize, however, that the recent tragic incident has, quite understandably, again generated considerable concern about package integrity and both tamper-resistant and tamper-evident aspects of product security.

In an effort to begin a careful consideration of the benefits and degrees of tamper-resistance of various types of orally administered over-the-counter products and packaging, during February 21 to 26, we held a series of informal meetings with various constituencies representing consumers, the health professional community, State and local authorities, encapsulaters and packaging experts, the pharmaceutical trade representatives and others who have been interested in this area.

These discussions have served as a beginning of our deliberate effort to accelerate the process of learning about contemporary dosage-form development, new ways of minimizing tampering attempts, the roles and comparative advantages to consumers of various dosage forms, and the perspective on this issue brought by different constituencies.

Essentially, we have utilized these meetings as a mechanism for obtaining a variety of outside views similar to the process we used previously in developing the action plan for FDA. I would like to illustrate some of the more important points that we learned and that individuals told me and our staff during these meetings.

First, tamper-resistant packaging for over-the-counter products, initiated in 1982, has added a clear layer of safety. Indeed, the safety record since that time is impressive.

Second, tamper-resistant does not mean tamperproof. The concept behind the 1982 regulations was to create packaging such that it would be more easily detected by the consumer if the product had been previously opened. However, no package is foolproof and a determined person may be able to penetrate even the most sophisticated of the packaging.

Third, there has been a continuing evolution of the technology involved in the development of new packaging systems resulting in improvements that may add an additional layer of safety to consumers.

Fourth, there was a call for better consumer awareness about examining packages and dosage forms. I believe this is an extremely important point and one that was emphasized continually throughout our meetings; and that is it is important for the consumer to look very carefully at the medicines that he or she is taking.

Tragically, in the case in Bronxville, it could have been determined that the capsules were tainted with cyanide as the white portion of the capsule was changed to a yellowish-brown hue from the contents of cyanide that were in the capsule.

Fifth, there was a consensus that FDA not take any precipitous action against any particular dosage form.

Sixth, there was a concern, especially among the elderly and disabled, that tamper-resistant packaging is already too difficult for some consumers to open.

Since the preparation of this testimony, we have received from our laboratory in Cincinnati information about the contents of the capsule that was found near the body of Timothy Green in Nashville, TN; and I communicated, in the early hours of this morning through the press, a summary of these events which I will introduce for the record.

[Information supplied follows:]

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

STATEMENT BY THE FOOD AND DRUG ADMINISTRATION
FOR IMMEDIATE RELEASE
Feb. 28, 1986

Bill Grigg (301) 443-3285
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FDA Commissioner Frank E. Young announced early this morning that FDA's Cincinnati laboratory has identified 91% sodium cyanide in the single capsule found near the body of Timothy Green in Nashville, Tenn. This is a different kind of cyanide from the potassium cyanide found in the capsules in the New York death of Diane Elsroth. The cyanide in the Nashville capsule also differs from any used in laboratories of the manufacturer of Tylenol, the tests established.

Nothing was found to indicate any connection between the Nashville death and that of Diane Elsroth in New York.

Commissioner Young said that FDA has no evidence that this is not an isolated local incident. FDA will continue working with the FBI and the Nashville authorities who are investigating this case. Nevertheless, Commissioner Young repeated his warning of Feb. 14 that consumers nationally should avoid Tylenol capsules of any lot number or type.

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Dr. Young. The type of cyanide in this case is sodium cyanide, 91 percent sodium cyanide, and this is different than the potassium cyanide found in the capsules in New York in the death of Dianne Elsroth. The sodium cyanide in the Nashville capsule is different from any used in the laboratories of the manufacturers of Tylenol, as our laboratory tests indicated.

Nothing was found to indicate any connection between the Nashville death and that of Dianne Elsroth in New York. FDA has no evidence that this is not an isolated local incident.

We are continuing to work with the FBI and the Nashville authorities who are investigating this case. Nevertheless, last night again I reiterated a call to all consumers that they should avoid Tylenol capsules of any lot in any strength.

Mr. Chairman, in closing I can only express the same concern that we all feel. The willful contamination of products intended to benefit consumers is repugnant to all of us.

I shall continue to work with other agencies in this investigation, and I pledge to conclude our review as expeditiously as possible. This concludes my prepared testimony.

I will be happy to answer any questions you may have.

[The prepared statement of Dr. Young follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

FRANK E. YOUNG, M.D., PH.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

February 28, 1986

FOR RELEASE ONLY UPON DELIVERY

Dear Mr. Chairman:

My name is Dr. Frank Young, Commissioner of the United States Food and Drug Administration (FDA). I am accompanied by John Norris, Deputy Commissioner, and Dan Michels, Director of the Office of Compliance, Center for Drugs and Biologics. We are here today to discuss with you actions taken by the FDA as national attention has once again focused on a cyanide-poisoning death related to the ingestion of Extra-Strength Tylenol capsules. We all mourn the tragic death of Diane Elsroth and offer our deepest condolences to her family and friends. As with the 1982 drug tamperings, it has been FDA's responsibility both to manage the immediate emergency situation, to support the ongoing investigation, and to review the broader issue of tamper resistance.

Mr. Chairman, our actions the week of February 10, 1986 were prompt and responsible. From the very first moment of this crisis, our first and foremost concern has been the protection of the public health. As described further below, when we learned of the discovery of a second bottle of Tylenol with cyanide-tainted capsules--from the Bronxville, New York area and from a different lot number than the first bottle--as a precautionary measure we immediately issued a public advisory to consumers nationwide urging not to use any Tylenol capsules of any lot or strength until more was known. Because the cyanide found in the second bottle was visible to the naked eye (i.e., a normally white capsule had a yellowish brown color), we urged consumers to take the extra precaution of examining all their medicines visually before use. In addition, because the type of cyanide found could remain stable inside capsules for several months, we were especially concerned about products already in people's home medicine cabinets and urged consumers to put Tylenol capsules out of the reach of children who may take them unknowingly.

In support of our public health mission, we have had our field investigators and laboratory analysts collecting remaining stocks from stores in the Greater Yonkers area and analyzing them for cyanide. Indeed, the so-called "second bottle" was removed from stocks at a retail store by an FDA investigator. We have also had FDA field personnel conduct comprehensive inspections of the manufacturing plants and distribution sites. These investigative activities also serve to support the criminal investigation being undertaken by the Federal Bureau of Investigation (FBI) under the Federal Anti-Tampering Act. At this time, I wish to recognize the close working relationship we have enjoyed with our colleagues in the FBI, as well as with State and local health and police authorities in New York. I also wish to acknowledge the full cooperation we have received from the Johnson & Johnson Company, the manufacturer of Tylenol.

We have also begun looking ahead at the broader issue of tamper resistance. Within the last seven days, we have already held six separate meetings with consumer group leaders, health care providers, industry trade associations, encapsulators and packagers, and State and local health officials. I would like to submit for the record a list of those organizations invited to these meetings. The purpose of these meetings has been to listen to the thoughts and responses of these various constituencies, and the results so far have been remarkable. Virtually everyone we met with understood the complexities of the situation and urged us not to take any precipitous action against any particular dosage forms. These groups recognize that tamper-resistant does not mean tamper-proof, and that it is difficult, if not impossible, to prevent this kind of dedicated criminal activity that appears to have occurred in New York. Finally, none of these groups saw new Federal regulations as the answer, but rather advocated improved consumer education and continued, evolutionary improvements in tamper-resistant packaging. We have profited immensely from these meetings, and we plan to hold several more over the next couple of weeks as we continue to look at the broader issue of tamper resistance.

Before going further, let me acknowledge the hard work and dedication of the many FDA employees, both in headquarters and in the field, who have been working literally around the clock to meet our public health responsibilities. This is a key example of where a strong FDA makes a real difference in the lives of all Americans.

CHRONOLOGY

Let me now summarize the chronology of events. On February 10, upon first learning of the death of a young woman in Yonkers, New York over the weekend, the FDA's Division of Emergency and Epidemiology Operations activated their emergency procedures. We also immediately began working in conjunction with the FBI and the local authorities in New York to investigate the death. An analysis of the capsules from the suspect bottle (lot number ADF-916) by the Westchester County Health Department revealed that these capsules were strongly suspected of containing cyanide. An analysis by FDA's New York Regional Laboratory of other bottles collected from the same A & P store where the suspect bottle had been purchased, and all other A & P stores in Westchester County however, did not reveal any tampering or cyanide in any other bottles. FDA headquarters, therefore, issued a statement on February 10 advising consumers in the Yonkers, New York area to avoid using Tylenol capsules and, as a special precaution, advised consumers nationwide to avoid Tylenol capsules bearing lot number ADF-916.

FDA's Philadelphia District Office contacted McNeilab, a division of Johnson & Johnson Company, the manufacturer of Tylenol, and informed them of the investigation. At the same time, we initiated communications with Dr. Millard J. Hyland and Dr. Lewis S. Roh, Medical Examiner and Deputy Medical Examiner of the Westchester County Health Department, and Dr. David Axelrod, Commissioner of Health of the State of New York, as well as with the company's management. Johnson & Johnson subsequently issued a press statement endorsing our consumer warning and established a "hot line" to enable consumers with questions to call the company toll free.

After testing all bottles of Tylenol from A & P stores in the immediate area, FDA expanded its sampling program and instructed investigators to collect all Tylenol capsules from all retail stores within a designated radius of the store where the original bottle had been purchased.

On Thursday afternoon, February 13, FDA's New York Lab identified cyanide in five capsules in a bottle of Tylenol Extra-Strength capsules (with a different lot number) which had been collected by FDA investigators from stock that had been on the shelves of an F.W. Woolworth store in the vicinity where the A & P bottle had been purchased. FDA immediately issued a second warning to the public advising consumers nationwide to cease using all Tylenol capsules of all lot numbers and all strengths. At this point, additional support was activated at other FDA district laboratories to expedite the analysis of the capsules which had been collected. In addition, field staffs nationwide were placed on emergency alert.

I would also like to submit for the record the two public statements I have just mentioned.

On February 17, 1986, Johnson & Johnson announced its decision to discontinue its manufacture and distribution of all drug products in capsule form sold directly to the consumer. The company offered to exchange, without charge, a new bottle of Tylenol caplets for any Tylenol capsules still in the hands of consumers. We respect their decision in this matter but it is important to point out that it was an independent decision on their part.

FIELD ACTIONS

Throughout the days that followed the first report of the death, FDA offered the resources of its field operation staff to support the FBI's ongoing criminal investigation. To date, over 1,770,000 capsules have been sampled and tested by FDA and Johnson & Johnson without any further evidence of cyanide contamination. Sample collection and laboratory analysis of Tylenol capsules continued on a 24-hour basis and the sampling effort was continuously expanded to cover an ever widening circle surrounding the vicinity of the death.

FDA also inspected all McNeil plants where Tylenol capsules are produced to determine whether the poison might have been introduced into the product during the manufacturing process. Based on the information gained from these inspections, there is no evidence to suggest that the tampering took place at the point of manufacture and, therefore, is anything other than a purely local incident.

Also, from the day Ms. Elsroth's death was first reported, my colleagues and I utilized national TV and radio news programs and other available means of communication to continue to advise consumers to avoid the use of Tylenol capsules. In this regard, I want to acknowledge the cooperation we have received from the press. This interaction enabled us to communicate critically important information rapidly and accurately to consumers.

REVIEW OF THE BROADER ISSUE OF TAMPER RESISTANCE

As you know, over three years ago, FDA was faced with the unprecedented malicious tampering with nonprescription drug products that resulted in the death of seven people in the Chicago area. In the weeks that followed that tragic event, the private sector and the Government worked together in a manner and at a pace never before experienced to develop and put in place improved packaging systems in an effort to provide additional safeguards for the benefit of the public health. Regulations requiring tamper-resistant packaging for certain over-the-counter (OTC) products were published approximately five weeks after the incident.

Under this regulation, manufacturers could choose among various techniques--seals, shrink bands, and bubble or strip packs, for example--but would be required to highlight the barrier with a distinctive design that would be hard to duplicate. This allowed manufacturers flexibility as to which methods of tamper-resistant packaging to use. It was also the intent to allow for newer methods being developed all the time to be included, as well as to encourage research and development of completely new protection methods.

As former Secretary Schweiker stated at that time, "While it is virtually impossible to make any package tamper-proof, it is possible to manufacture packages in such a way that tampering is much more difficult, and that if a product is tampered with, it can more easily be detected by a careful consumer." Since that time there has been a continuing effort on the part of industry to improve upon the existing packaging systems.

This recent incident has, quite understandably, again generated considerable concern about package integrity and both tamper-resistant and tamper-evident aspects of product security.

In an effort to begin a careful consideration of the benefits and degrees of tamper resistance of various types of orally administered OTC products and packaging, during February 21-26, we held a series of informal meetings with various constituencies representing consumers, the health professional community, State and local authorities, encapsulators and packaging experts, and pharmaceutical trade representatives who have an interest in this area. These discussions have served as the beginning of a deliberative effort to accelerate the process of learning about contemporary dosage form development, new ways of minimizing tampering attempts, the roles and comparative advantages to consumers of various dosage forms and the perspectives on this issue brought to bear by these different constituencies.

We have utilized these meetings as a mechanism for obtaining a variety of outside views directly, similar to the process we used previously in the development of the FDA's Action Plan. Some of the points suggested by most meeting participants included the following:

- Tamper-resistant packaging for OTC products, initiated in 1982, has added a clear layer of safety. Indeed, the safety record since that time is impressive.

- Tamper-resistant does not mean tamper-proof. The concept behind the 1982 regulations was to create packaging such that it would be more easily detected by the consumer if the product had been previously opened. However, no packaging is foolproof, and a determined person may be able to penetrate even the most sophisticated packaging.

- There has been a continuing evolution of the technology involved in developing new packaging systems resulting in improvements that may add an additional layer of safety to consumers.

- There was a call for better consumer awareness about examining packages and dosage forms before use. This was especially true since the cyanide in the Tylenol capsules changed the color of the capsule from white to yellowish brown so that it would have been visible to a consumer.

- There was also a consensus that FDA not take any precipitous action against any particular dosage form.

- There is concern, especially among the elderly and the disabled, that tamper-resistant packaging is already too difficult for some consumers to open.

CONCLUSION

In closing, I can only express the same concern we all feel. The willful contamination of products intended to benefit consumers is repugnant to us all. I shall continue to work with other agencies in this investigation and I pledge to conclude our review as expeditiously as possible.

Thank you Mr. Chairman. This concludes my prepared testimony. I will be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Dr. Young.

Let's turn now to Mr. O'Hara.

Mr. O'HARA. Thank you, Mr. Chairman. Good morning, Mr. Chairman, Senator Kennedy, Senator Metzenbaum.

I appreciate the opportunity to appear this morning to represent the FBI and Judge Webster to discuss the FBI's role in investigating reported violations of the Federal Anti-Tampering Act.

In response to the tragic Tylenol poisoning deaths in the Chicago area in the fall of 1982, Congress enacted the Federal Anti-Tampering Act, Public Law 98-127, which became effective on October 13, 1983, and created the new section 1365 in title XVIII, United States Code, entitled "Tampering with Consumer Products."

Under the provisions of this act and in addition to the FBI's general investigative powers, the FBI, the FDA and USDA investigate tampering violations involving consumer products under each respective authority.

We have developed operational procedures in concert with each agency so that we are able to individually and collectively discharge our responsibilities in an effective manner with a minimal amount of duplication of effort. We work closely with our colleagues in FDA and USDA, and strive to resolve complaints of actual or alleged acts of tampering in the shortest possible time.

Similarly, as in the Nashville case, we work hand in hand with local and State authorities as well. This is true not only in the investigative phase of the process, but in the prosecutorial phase.

Our agreements with the FDA and the U.S. Department of Agriculture regarding each agency's investigative responsibilities can best be summarized as follows:

With regard to FDA responsibility, the Food and Drug Administration will investigate all consumer complaints including those concerning possible tampering, tainting or adulteration of products under its regulatory control. If the FDA investigation determines that the tampering in question is not an isolated incident and the public is exposed to a risk, or an extortionate demand is involved in the tampering process, the matter will be referred to the FBI for appropriate examination—investigation.

As far as USDA's responsibility is concerned, the USDA has regulatory authority and responsibility over meat, poultry, and egg products, and investigates reports of tampering with these products. Our agreement with the USDA in this area requires that those cases involving a threat to tamper with meat, poultry, or egg products and/or those involving an extortionate demand to tamper with such products are referred to us, the FBI, for investigation.

As far as our responsibility, Mr. Chairman, the FBI will investigate those cases that involve a serious threat to human life.

The CHAIRMAN. Mr. O'Hara, let me just save us some time here.

Mr. O'HARA. Yes.

The CHAIRMAN. We will put your full statement in the record because you do chronicle a lot of the history on what the FBI has done and what you are doing, and some of the cases that have arisen that you have investigated.

Mr. O'HARA. All right.

The CHAIRMAN. I think all we need to know is where you are on these latest incidents of tampering with regard to Tylenol. If you could, just tell us whatever you can there.

We realize that you have an ongoing investigation and you may be limited in what you can tell us, but we would like to hear what you have to say.

Mr. O'HARA. I am constrained somewhat, Mr. Chairman, by the fact that these are pending investigations. However, I will concur with what Dr. Young indicated: that our investigation has not indicated any tie between the death in Nashville, which was recently reported, and the acts in Bronxville, New York.

There is a significant difference in the composition of the cyanide poison.

Our investigation continues in New York. We have not developed a suspect or suspects in the investigation. We have developed a task force working with New York State Police. We have developed a game plan for the long haul.

We don't anticipate this is going to be an easy investigation as, certainly, the Chicago investigation—which is still pending—has shown us: that these do not generally come to a quick end in most instances.

We are collecting samples with FDA of cyanide poison in the area to compare them with the product that was recovered from the capsules. We continue to examine bottles. We continue to respond to aggravated employees who have left Johnson & Johnson. We look at them for possible suspects.

There was a suspect developed earlier—I said we didn't have a suspect—as a result of an arrest made and a letter found that was directed to the police in the Yonkers area. We have not tied that person at all to the death of Dianne Elsroth.

Our examinations in the laboratory continue. We did make a statement with regard to tampering that has been discovered as a result of the FBI laboratory examination. I cannot get into the way that our examination discovered the tampering other than to say that we have confirmed that we have located evidence of tampering with the Tylenol bottles in the Elsroth death.

The CHAIRMAN. Thank you, Mr. O'Hara.

[The prepared statement of Mr. O'Hara follows:]

U.S. Department of Justice

Federal Bureau of Investigation

Washington, D.C. 20535

STATEMENT

OF

SPECIAL AGENT NICHOLAS V. O'HARA
CHIEF, GENERAL CRIMES SECTION
CRIMINAL INVESTIGATIVE DIVISION
FEDERAL BUREAU OF INVESTIGATION

BEFORE

THE

LABOR AND HUMAN RESOURCES COMMITTEE
UNITED STATES SENATE

CONCERNING THE

FEDERAL ANTI-TAMPERING ACT

FEBRUARY 28, 1986

Mr. Chairman, I appreciate the opportunity to appear before you today to discuss the FBI's role in investigating reported violations of the Federal Anti-Tampering Act.

In response to the tragic Tylenol poisoning deaths in the Chicago area in the fall of 1982, Congress enacted the Federal Anti-Tampering Act, Public Law 98-127, which became effective on October 13, 1983, and created Section 1365 in Title 18, United States Code, entitled "Tampering with Consumer Products." Under the provisions of this act, and in addition to the FBI's general investigative powers, the FDA and USDA investigate tampering violations involving consumer products under their respective regulatory authority. We have developed operational procedures in concert with each agency so that we are able to individually and collectively discharge our responsibilities in an effective and efficient manner with a minimal amount of duplication of effort. We work closely with our colleagues at FDA and USDA, and strive to resolve complaints of actual or alleged acts of tampering in the shortest possible time.

Similarly, we work hand in hand with local and state authorities as well. The act does not grant exclusive jurisdiction to the Federal Government. Thus, in tampering cases, as in many, indeed, most other criminal violations, both Federal and state interest must be accommodated. This is true not only in investigatory phases of a case, but in the prosecutive stage as well.

Our agreements with the FDA and the USDA regarding each agency's investigative responsibilities can be summarized as follows:

FDA Responsibility

The FDA will investigate all consumer complaints, including those concerning possible tampering, tainting or adulteration of products under its regulatory control. These types of complaints generally come from persons who purchase a product and later discover it appears to contain a foreign object or substance. Many such complaints can be traced back to a manufacturing, packaging, or shipping problem, and while the product may be unpalatable or offensive it is not necessarily harmful. Ice crystals in ice cream are a common example of such a problem since they have been mistaken for shards of glass. If the FDA investigation determines that the tampering in question is not an isolated incident and the public is exposed to a risk, or an extortionate demand is involved in the tampering process the matter will be referred to the FBI for appropriate investigation.

USDA Responsibility

The USDA has regulatory authority and responsibility over meat, poultry and egg products, and investigates reports of tampering with those products. Complaints generally come from persons who purchase a product and later find an object in it such as a piece of metal or bone. As in the case of the FDA, the USDA investigates the complaint to determine if it was caused by a processing error or deliberate tampering. USDA investigators have law enforcement authority and may bring criminal cases to a United States Attorney for prosecution when sufficient facts are developed for such action. Our agreement with the USDA requires that those cases involving a threat to tamper with meat, poultry or egg products, and/or those involving an extortionate demand to tamper with such products, are referred to the FBI for investigation.

FBI Responsibility

The FBI will investigate those cases that involve a serious threat to human life. Complaints involving a death will be immediately investigated by the FBI to determine if a violation of Section 1365 exists. The FBI will also investigate those matters involving threatened tamperings and actual or threatened tamperings coupled with an extortionate demand.

We have found these agreements and guidelines to be practical, effective, and with the free exchange of information we have at all levels with the USDA and the FDA, very workable.

Since Section 1365 became effective in October, 1983, the FBI has, in Fiscal Years 1984 and 1985, opened 114 cases and expended over 20,000 Special Agents work hours investigating them. While the figures for FY 1986 are incomplete, the FBI has expended over 16,500 Special Agent workhours in the recent Yonkers, New York, case alone. These figures are an indication as to the variables in this area, and the difficulty in projecting resource requirements to meet the challenge. The information does show, however, that we react immediately in these types of cases and ensure that all necessary resources are committed to them to address the problem.

From a historical standpoint, the first Federal conviction obtained under Section 1365 was the result of an investigation which began in February 1984. This case involved an individual in Pueblo, Colorado, who called the regional office of a major grocery store chain, stating he had placed "enough cyanide in all the stores to kill at least 100 families." The caller demanded a payment of $500,000. The individual called again the next day to repeat his threats and demands, and gave instructions as to where the money should be placed. FBI Agents had placed the payoff location under surveillance and subsequently arrested two men who attempted to take a package they thought contained the $500,000. Intensive investigation over the weekend of February 24-26, 1984, led to the identification and arrest of a third individual who was responsible for creating and placing this plan in motion.

Charges against one of the men arrested at the payoff site were dismissed as it was learned he had merely gone along on the scheme at the request of his friend, and he was not involved in the crime. On March 5, 1984, the two subjects directly involved in this scheme were indicted for violating the Hobbs

Act-Extortion Statute. After the evidence against the main subject in this matter was revealed, his attorney negotiated a plea bargain agreement with the U. S. Attorney in which the defendant agreed to plead guilty to two counts of violating Section 1365. On July 10, 1984, this subject, aged 62 years, appeared in U. S. District Court and was ordered to the Medical Center for Federal Prisoners at Springfield, Missouri, for examination before being sentenced. On October 24, 1984, he returned to the court where his sentence was imposed: a $5,000 fine and five years probation. The principal subject's accomplice, a relative, was granted a pretrial diversion agreement and he was placed on one year probation in view of his age (21), and circumstances of his involvement in this matter.

In another case that began in February, 1985, a major tobacco company in North Carolina received three letters in which the writer threatened to put an unnamed poison in the company's cigarettes throughout the United States unless it sent 20 envelopes containing $5,000 cash each to a certain post office box in Montana. Our offices in Charlotte, North Carolina, and Butte, Montana, entered the case immediately, and by February 18, 1985, had identified and located the three individuals involved in this matter. The "mastermind" of this scheme pleaded guilty to violating Section 1365 and was sentenced to five years in prison. The other two individuals had generally aided and abetted the main subject, and were allowed to enter into a 12-month pretrial diversion agreement with the U. S. Attorney.

In a third case that began on May 10, 1985, an individual telephonically contacted the corporate office of a major grocery store chain in Tennessee, and demanded $100,000 for Vietnam veterans or sodium cyanide would be put into the chains packaged foods. The individual made a number of additional calls to repeat his threats and demands, and gave instructions for making the payoff in a heavily wooded rural area. On May 14, 1985, after maintaining discrete surveillance of the payoff location for a number of hours under extremely difficult conditions, FBI Agents arrested the subject as he picked up the extortion package. On May 22, 1985, he was indicted for violating Section 1365, and on August 29, 1985, he pleaded guilty to this offense in U. S. District Court, Nashville, Tennessee. In view of his age (62) and the fact that he had no known prior criminal record, he was sentenced to 3 months in the custody of the Attorney General, 3 months in a half-way house, and 4 1/2 years probation.

In yet another case during November, 1985, corporate officials of a chain of restaurants in Atlanta, Georgia, began receiving a series of letters demanding $650,000 or patrons of the restaurants would be poisoned. The extortionist's payoff instructions were elaborate, innovative and somewhat unique. He told an official at the victim company to proceed alone at night, with the money, to a series of locations where he would find additional directions as to where to leave the funds. The last step required the company official to walk approximately half-way across a certain bridge and lower the money by rope down to the water. We were able to maintain surveillance of this situation, by using a number of specialized and sophisticated techniques, and arrested the subject as he swam to shore clad in a wet suit. After being arrested, the subject's vehicle was searched and sugar packets and a salt shaker from one of the threatened restaurants and cyanide and arsenic were found in his vehicle. A hypodermic needle was located in the subject's hotel room. He has been indicted for violating Sections 1365 (Tampering), 1951 (Hobbs Act-Extortion) and 876 (three counts of Extortion). His trial is scheduled to begin March 17, 1986, in U. S. District Court, Atlanta, Georgia.

We are proud of the accomplishments achieved thus far in investigating violations of the Federal Anti-Tampering Act as exemplified by the case summaries which I have outlined. We realize that not all cases end so successfully and will continue to pursue all violations in a vigilant and dedicated manner. I wish to especially mention the outstanding assistance and cooperation we receive from product manufacturers, commercial firms, and others who may be victimized or threatened during offenses under Section 1365. This outstanding cooperation and assistance is also evident in our relationships with U. S. Attorneys, the FDA and the USDA. I believe this spirit of total cooperation abundantly shows the Federal government's broad commitment to move aggressively against anyone who would violate

Section 1365, and attempt to endanger the public with acts which cause serious injury or death.

It should be noted that considerable work is often required not only by the FBI, but by FDA, USDA and product manufacturers, to determine that no actual product tampering did occur.

In pursuing our investigations under Section 1365, we are confronted with a wide variety of scenarios. To best illustrate this, we can look at the last 20 cases the FBI was involved in :

17 involved a threat to tamper;

15 of those were threats to poison products

1 was to put a laxative into a product.

1 was to release fruit flies in a number of states where fruits, vegetables and other types of produce are grown.

Of these 17 threat cases, 7 had an accompanying extortionate demand tied to them.

The three remaining cases involved consumer complaints made after the product was purchased. These involved apparent deliberate acts of tampering without an accompanying threat or extortionate demand.

Of these three cases:

1 involved urine and another substance in a fruit drink

1 involved a caustic substance in eye drops

1 involved a toxic substance found in syrup

The FBI will address every case of alleged product tampering which comes to our attention by referral or other means and each case will be given immediate, aggressive and continued attention. While unfortunately we do not resolve every case referred to us, since a number of cases are opened on initial demand and no follow-up activity is forthcoming, we consistently make an early commitment of necessary resources to identify and apprehend those persons who would attempt such crimes. In the investigations which I have mentioned, most of them were completed within a few days and our success in these matters is directly related to the outstanding cooperation and assistance we receive from United States Attorneys and numerous other Federal, state and local agencies.

As you know, the FBI is presently investigating a case in Yonkers, New York, which involves product tampering. This is one of our most important investigations and we are making a maximum effort to solve it. Due to the pendency of this investigation, I am restricted in my comments about it.

This concludes my opening remarks and I will try to answer any questions which you may have.

The CHAIRMAN. Let's turn to Ms. Dawson at this time.

If you could also summarize, Ms. Dawson, we would appreciate it.

Ms. DAWSON. Good morning, Mr. Chairman.

The CHAIRMAN. Good morning.

Ms. Dawson. I am here today to present the Consumer Product Safety Commission's views on the tragic situation which has arisen with respect to the criminal contamination of Tylenol capsules. Inasmuch as the Food and Drug Administration has primary jurisdiction in this area, my remarks will be brief.

In 1982 when the issue of tampering with over-the-counter drugs arose, the Commission discussed with the FDA the authority of the respective agencies to respond to this serious problem. While the Commission administers the Poison Prevention Packaging Act of 1970 with respect to drugs, that statute deals solely with packaging design to limit access to hazardous household substances by children under age 5.

Several over-the-counter drugs, including acetaminophen capsules, must be specially packaged, but the act does not contain authority to mandate tamper-evident packaging: the use of packaging techniques which will result in visible evidence if the package has been opened prior to consumer purchase.

Accordingly, the Commission's role has been to assist the FDA, which has been the lead agency in handling the matter. FDA subsequently adopted requirements for tamper-evident packaging for over-the-counter drugs and other products.

During the last 3 years, the Commission has provided technical assistance to the FDA in evaluating tamper-evident packaging. The primary objective of CPSC has been to insure the incorporation of tamper-evident packaging features which do not compromise the effectiveness or utility of child-resistant caps used on over-the-counter products regulated under the Poison Prevention Packaging Act.

We have also worked with FDA to evaluate the ability of older consumers to use products with tamper-evident features.

The Commission has developed considerable expertise over the last 13 years in the evaluation of packaging for all types of products, including over-the-counter drugs. We stand ready to provide whatever expertise we can to our sister agency to assist in preventing the recurrence of such a terrible event.

With me today is Michael Gidding of my office and other Commission staff who are available to answer any questions concerning jurisdictional or technical questions presented by this contamination problem.

The CHAIRMAN. Well, thank you.

Let me just ask some questions of you, Dr. Young.

What is your view of the current level of safety of over-the-counter drug packaging; and can it be improved substantially?

Dr. YOUNG. We feel that there is a great degree of safety in the current over-the-counter packaging and there is not the room for improvement that there was following the Tylenol crisis in Chicago when packages were opened.

There are additional improvements that can be made, but I must emphasize they are important but not as dramatic as earlier gains.

The CHAIRMAN. I see. Now, the steps that have been taken by the various manufacturers, are they sufficient in your view?

Dr. YOUNG. We feel that there are a number of steps that have been taken that are very fine, but it is important to emphasize that no particular package is tamperproof. There have been particular advances that have gone beyond what was present in 1982.

For example, the seals on some of the liquids have been replaced by metal caps that tear off. In other instances, a complete paper foil has been inserted behind a blister pack.

All of these provide a level of safety, but none of them provides an absolute tamperproof package.

The CHAIRMAN. Do you think industry might consider other steps that they have not considered thus far to upgrade the safety of over-the-counter packaging?

Dr. YOUNG. Yes; we do. We feel that this is an evolutionary process. I have been impressed, as we have reviewed this and Mr. Michaels has been working with the Proprietary Association on the technical committee to see some of the changes.

As I mentioned, the replacements that have occurred over the period of time, particularly the improvement in adhesive materials for the blister packs, the ability to make capsules that are also sealable—and I have some examples of those if you would like to see those—and there are a number of advances that can be made; but we have made a very large advance in 1982 and we are now going further, with important additional steps.

The CHAIRMAN. Is the FDA doing anything to stimulate further advances or further technological approaches to this?

Dr. YOUNG. The very meetings that I held to find out information from not only the consumers and professionals but also the trade associations were designed to stimulate the communication between FDA and industry. Also, we do have the committee that Mr. Michaels is on.

We feel this is a valuable way of bringing industry and Government together to look for improvements in the new technologies that can be added.

The CHAIRMAN. Do you foresee any changes in FDA regulations in this area to assure drug safety and the prevention of tampering by anybody?

Dr. YOUNG. At this point, the information and advice that I have received in my own informal meetings are that no additional regulations are required, at this time. The important emphasis on this is to point out how far we have gone.

Thus, I believe this was broadly recognized by the groups that I had met with who, to a person, emphasized no additional regulations.

The CHAIRMAN. Do you think there should be an effort similar to the cooperative efforts that we had between the FDA and the manufacturing community with regard to Reyes syndrome to conduct, say, a public education campaign?

Dr. YOUNG. It was interesting, Senator, that the major emphasis that came out over and over again, particularly from the consumer groups, is the need to provide better educational material. The USP had developed, in 1982, a pamphlet called "Tips Against Tampering"; and part of the consumer meeting that I had was to see how we could decide and design a better pamphlet that was not so laborious and cumbersome that might be able to be distributed to consumers.

I think there is a great advance that can be taken. In fact, there was an emphasis that we are in a time window that we should utilize now in getting that information out to the public.

The CHAIRMAN. Now, 11 days ago the Westchester County executive, Andrew O'Rourke, called for a Federal ban in sale and distribution of all nonprescription capsules. In addition, as an alternative to an outright ban on capsules, he urged that capsules be made in single units, not in pull-apart units, and that they be sold only from behind the counter in pharmacies and other outlets.

Would you comment on Mr. O'Rourke's proposal, Dr. Young?

Dr. YOUNG. Yes. Let me demonstrate a few of these if I could, sir.

There are a variety of capsules, first of all, that can be developed and are in development or, in fact, in use. This particular one has a band and seals the two particular joints.

The CHAIRMAN. It's very difficult to pull apart.

Dr. YOUNG. It is very difficult to pull apart. In fact, when we try, we frequently——

Senator KENNEDY. Can I ask you, why don't you require that, then?

Dr. YOUNG. If I could demonstrate them, Senator, and then come to that particular point in just a moment.

There are other capsules that are smaller in structure, and these are sealed by a solvent. Their shape is very small and it's very, very hard to grab these and even to pull them apart.

Someone asked a question earlier about the sonically sealed capsules. One of the complaints that we had was, because the capsules were sonically sealed they leave an imprint in the capsule which looks like a damaged capsule.

These, too, are very hard to pull apart without breaking them.

At the moment, we are looking—Senator Kennedy, to get to your question—to evaluate whether or not this provides such a layer of safety that anything should be done further. I must also point out that as with any dosage form we have no reason to believe at this time that the very dedicated person might not be able to circumvent these layers of safety as well.

The CHAIRMAN. Let me just ask you one last question, then I would like to move to Mr. O'Hara.

How is the poison, sodium cyanide, different from potassium cyanide? You have indicated a difference in these two instances here.

Dr. YOUNG. We are able to use some very sophisticated techniques to fingerprint the other trace materials that are in the cyanide samples. That enables us to determine whether the batches are similar in the two cases.

In the case of the bottle that we found on the premises where Ms. Elsroth died, we could compare a complete match between that and the second bottle that was found in the Bronxville area. By similarly using these methods, we were able to determine that the Tennessee capsule was different both chemically and in its fingerprints, if you will; and they were different from the Chicago case.

The CHAIRMAN. I see. Let me just address this next question to both you and Mr. O'Hara since I think it applies to both of your agencies.

First, is the drug, or over-the-counter, tampering problem much more widespread than we have been led to believe?

Dr. YOUNG. I have some statistics on that that I can provide for you.

We looked at the years that would give us some followup for the particular time that we are concerned with. I would like to get these for you.

We found, yes, that in 1983 there were 137 reports which were confirmed out of 737 reports to the agency. In 1984, 74 were confirmed out of 487. In 1985, 20 were confirmed out of 128.

The CHAIRMAN. This does not necessarily mean confirmed with Tylenol or the same substance.

Dr. YOUNG. No.

The CHAIRMAN. You are talking about all tamperings.

Dr. YOUNG. This is any type of tampering. So that if one looks at the amount of tampering, one can conclude that since the peak, following Chicago when we would expect a number of copycats, this has decreased.

In fact, we feel that the very low level of copycats that we had this time shows that the consumers are protected by the tamper-resistant packaging. It takes a dedicated person, now, to put something in a package rather than the very easy tampering that occurred after the Chicago incident.

The CHAIRMAN. Is that your experience, Mr. O'Hara, as well?

Mr 'O'Hara. I would have to rely very much on Dr. Young's comments in terms of that.

The CHAIRMAN. Are there cases in which death or injuries are attributed to other causes which may have been over-the-counter poisonings?

Dr. YOUNG. We have looked at that and we do not find any over-the-counter deaths that we could identify other than the one that we received information on: the tragic death of Ms. Elsroth.

It is important to point out that during this period of time approximately 100 billion capsules were sold per year in the United States and throughout the world in both prescription and as over-the-counter forms. In the field of analgesics since 1983, 12½ billion capsules have been sold.

This is the first episode.

One can compare this, as poor as it is, statistically with some common deaths. Death from automobiles is approximately, per annum, 1 per 24,000; deaths from accidents within the home about 1 per 11,000.

So the poor statistics, because it is fortunately not a large number of people, show that capsule use and over-the-counter medicines, in general, have a very, very high level of safety.

The CHAIRMAN. Are the legal tools available sufficient to deal with this type of a problem: tampering of over-the-counter drugs? Do you need additional legal authority, or are there remedies that you have right now in the Tampering Act, which we passed after the 1982 incidents, sufficient to give you enough law enforcement authority to solve these problems?

Dr. YOUNG. From the standpoint of FDA, we have been very pleased with the authority that we have had and very pleased with the cooperation with FBI. We have a memorandum of understanding on the ways that we investigate. This is in the statement of the FBI.

I believe that we have, for our own part—which is the investigation of consumer complaints and the scientific aspects of the study—adequate authority.

The CHAIRMAN. Do you agree, Mr. O'Hara?

Mr. O'HARA. Senator, with the advent of the Tampering Act, we have been allowed access to cases we might not have been in before. The Tampering Act has been very advantageous in assisting us in our jurisdictional——

The CHAIRMAN. Well, re-examine that. If you think you need more authority, there are four members of the Judiciary Committee on this committee and, of course, most of us were responsible for passing that law back in 1982.

We would love to have any suggestions you have that might upgrade the law or make it even more accessible to you or beneficial to you and the public.

Dr. YOUNG. Thank you. We shall.

The CHAIRMAN. Thank you.

Should there be more severe restrictions on the sale of cyanide or other toxic substances? Do you think that may be one of the ways we can solve this problem?

Dr. YOUNG. This is a very difficult issue. I have looked into this following the identification of the cyanide and tried to analyze it to some degree.

Cyanide is quite widely available in a number of ways. I will not detail all of them. Suffice it to say that it is accessible in commercial trade, accessable through research laboratories.

Actually, we have seen some pamphlets advertising the sale of cyanide, which we have turned over to the FBI in one particular incident.

It is hard, in the degree of availability of cyanide, to see ways in which we could completely cut if off; but certainly there are ways in which we should worry, at least, how free an access this might be. But because of its widespread industrial use, I have difficulties imagining at this point how it is best to construct any action.

The CHAIRMAN. Thank you.

Let me just ask one question of you, Ms. Dawson, and I will turn to Senator Kennedy.

Do you have any legislation or regulatory initiatives that you feel are necessary to help us to achieve our goal of more safety to consumers?

Ms. DAWSON. I think I would have to concur with Dr. Young's statement. I think because FDA has the primary jurisdiction in this field, we would support his position.

The CHAIRMAN. All right. Thank you.

Let's turn to Senator Kennedy.

Senator KENNEDY. Thank you very much, Mr. Chairman.

Just to come back to an earlier question about what the consumers ought to understand as the degree of safety when they go into the drugstores or supermarket, what can you tell us?

Is it somewhat safe? Are you satisfied it is extremely safe?

Dr. YOUNG. I think it is extremely safe, Senator. It is impossible, as Senator Metzenbaum mentioned in one of his interchanges earlier with the Mr. Clare of Johnson & Johnson, to make sure there is 100-percent safety; but looking at the record, I think this is an extremely safe condition.

Senator KENNEDY. Now, you indicated in your testimony, on page 3, "Virtually everyone we met with understood* * *." Let me establish a premise.

You are not prepared to make a recommendation today that there should be any change in safety regulations by the FDA to protect the consumers.

Dr. YOUNG. That is correct.

Senator KENNEDY. That is your position.

Dr. YOUNG. That is correct.

Senator KENNEDY. You elaborate on that on your page 3 where you say, "Virtually everyone we met with understood the complexities of the situation and urged us not to take any precipitous action against any particular dosage forms."

Do I gather, then, that everyone that you met with said that no new Federal regulations were necessary?

Dr. YOUNG. First, I would like to emphasize that I would not call this a comprehensive study at this point.

Senator KENNEDY. Well, why not? Why not a comprehensive study?

Dr. YOUNG. No; I'm sorry. My page 3 statement.

I wanted to develop as rapid a method of getting information as I could and, therefore, met with representative groups.

Senator KENNEDY. So your testimony, then, is not definitive. Do I gather that?

Dr. YOUNG. No, sir. It is very definitive; but I wanted to give the caveat that, at this time, through all of the individuals that I had met with, the overwhelming advice that I received was that one should not take precipitous action against any particular dosage form.

Senator KENNEDY. Well, will you tell us who dissented and for what reason they dissented in these informal meetings?

Dr. YOUNG. There was no dissension, sir.

Senator KENNEDY. So it was unanimous in the recommendations that you have had from these meetings with the experts in this area that there was no suggestion that there be an alteration or change in the safety regulation.

Dr. YOUNG. This was particularly true——

Senator KENNEDY. Could I get yes or no on that.

Dr. YOUNG. Yes; and this is particularly true of Mr. Shultz, and I want to submit these for the record.

Senator KENNEDY. Will you be kind enough to indicate to the committee who you did meet with, the names of the people that you did meet with.

Dr. YOUNG. Yes; I have the complete list with me.

Senator KENNEDY. Not now; just make it a part of the record, if you would.

Dr. YOUNG. Absolutely, and that is what I mentioned earlier.

[Information supplied for the record follows:]

MAR 0 7 1986

The Honorable Orrin G. Hatch
Chairman, Committee on Labor
and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

In response to your and Senator Kennedy's letter of February 28 and as discussed at the Tylenol hearing, enclosed is a list of the attendees at the six meetings I have held over the past three weeks with consumers, health professionals, encapsulators and packagers, trade associations, and State officials. Enclosed you will also find memoranda which summarize the opinions and suggestions raised at these meetings. The major points raised, which I summarized in my testimony, are remarkably consistent across these different groups.

As I mentioned at the hearing, I plan to hold several more of these meetings and to conclude my study of this issue within the next two to four weeks. I will be pleased to brief you and your staff more fully at that time. These meetings are providing us with a very good understanding of the public's expectations and opinions on the safety of over-the-counter drug packaging and different dosage forms, and what additional steps--such as increased consumer awareness and evolutionary improvements in tamper-resistant packaging--would be appropriate to provide an additional layer of safety to the American public.

John Norris and I appreciated the opportunity to appear before you last week to discuss this extremely important public health issue. I have sent a similar letter to Senator Kennedy.

Sincerely yours,

Frank E. Young, M.D., Ph.D.
Commissioner of Food and Drugs

2 Enclosures
List of Attendees
Minutes of Meetings

ORGANIZATIONS ATTENDING THE
COMMISSIONER'S MEETING WITH HEALTH CARE PROVIDERS
TYLENOL TAMPERING

February 21, 1986
9:00 - 10:30 a.m.
Commissioner's Conference Room, FB-8

American Medical Association

Dr. Kenneth Lampe

American Academy of Family Physicians

Ms. Rosemarie Sweeney

American College of Physicians

Ms. Deborah Prout

United States Pharmacopeia

Dr. William Heller
Mr. Joseph Valentino

American Hospital Association

Dr. Tim Redman

American Pharmaceutical Association

Dr. John Schlegel
Ms. Glenna Crooks

Institute of Medicine

Dr. S. Thier

ORGANIZATIONS ATTENDING THE
COMMISSIONER'S MEETING WITH CONSUMER GROUPS
TYLENOL TAMPERING

February 21, 1986
11:00 a.m.
Commissioner's Conference Room, PKLN

American Association of Retired Persons
Ms. Judy Brown

Arthritis Foundation
Mr. Robert Humphreys

Consumer Federation of America
Ms. Mary Ellen Fise

Federation of Homemakers, Inc.
Ms. Nancy Bowers

National Coalition of Hispanic Mental Health and Human Services Org.
Mr. Bill Bogan

National Consumers League
Ms. Linda Golodner

National Council of Negro Women
Ms. Margie Word

National Council of Senior Citizens, Inc.
Mr. Chris Papps

National Council on the Aging, Inc.
Ms. Susan Abbott

National Urban League
Ms. Suzanne Bergeron

Public Voice for Food and Health Policy
Ms. Diane Barzman

Public Citizen Litigation Group
Mr. William Schultz

Retired Persons Services, Inc. (Pharmacy)
Ms. Nancy Olins

U.S. Office of Consumer Affairs
Ms. Juanita Yates

ORGANIZATIONS ATTENDING THE

COMMISSIONER'S MEETING WITH FOOD TRADE ASSOCIATIONS

TYLENOL TAMPERING

February 24, 1986
11:00 a.m.
Commissioner's Conference Room, PKLN

Food Marketing Institute
- Anne McChee - Sr. Gov. Relations Representative
- David Richman - Director of Quality Assurance, Giant Food

National Association of Convenience Stores
- Mr. K. Grahl

Association of General Merchandise Chains
- Edward T. Borda - President

American Retail Federation
- Lloyd Hackler - President

Grocery Manufacturers of America
- George W. Koch - President
- Sherwin Gardner - Vice-President, Science & Technology

Council for Responsible Nutrition
- J. B. Cordaro

Private Label Manufacturers Association
- Mr. D. Eldredge

ORGANIZATIONS ATTENDING THE
COMMISSIONER'S MEETING WITH ENCAPSULATORS AND PACKAGERS
TYLENOL TAMPERING

February 24, 1986
1:30 p.m.
Commissioner's Conference Room, PKLN

Eli Lilly and Company
Mr. E. Davis
Mr. R. Williams
Mr. A. Carnaghi

R. P. Scherer Company
Mr. D. Davies
Mr. R. Jimerson

American Can Company
Mr. P. VanKeuien
Mr. R. Schofield

Warner-Lambert Company
Mr. Yakatan
Mr. C. Hoover

ORGANIZATIONS ATTENDING THE
COMMISSIONER'S MEETING WITH DRUG TRADE ASSOCIATIONS
TYLENOL TAMPERING

February 24, 1986
3:30 p.m.
Commissioner's Conference Room, PKLN

National Association of Retail Druggists
- Charles West - Executive Vice-President
- John Rector - Gen. Counsel & Vice-President of Gov. Affairs
- Todd Dankmyer - Vice-President, Communications

National Association of Chain Drug Stores
- John Kelley - Vice-President, Gov. Affairs
- Marsha Millonig - Director, Pharmacy Affairs

American Society for Hospital Pharmacists
- Linda Harteker - Director of Public Information

American Pharmaceutical Association
- Glenna Crooks - Director, Policy Division

Proprietary Association
- R. William Soller, Ph.D. - Vice-President, Scientific Affairs
- Edwin C. Mulcahy - Assoc. General Counsel

National Association of Pharmaceutical Manufacturers
- George Schwartz - Executive Director
- Niles Barry - President

Pharmaceutical Manufacturers Association
- Mr. N. Mulcahy
- Dr. J. Jennings

ORGANIZATIONS ATTENDING THE
COMMISSIONER'S MEETING WITH STATE AND LOCAL HEALTH OFFICIALS
TYLENOL TAMPERING

February 26, 1986
2:30 p.m.
Commissioner's Conference Room, PKLN

Association of State & Territorial Health Officers
Bernard J. Turnock, M.D., M.P.H.
Director, Illinois Dept. of Public Health

Association of Food and Drug Officials
Jack B. Ogun
Director, Div. of Drugs, Devices & Cosmetics
Bureau of Quality Assurance
Pennsylvania Dept. of Health

National Association of Boards of Pharmacy
David R. Work
Executive Director
North Carolina Board of Pharmacy

ORGANIZATIONS INVITED TO THE COMMISSIONER'S MEETING WITH CONSUMER GROUPS

TYLENOL TAMPERING

February 21, 1986
11:00
Commissioner's Conference Room, PKLN

American Association of Retired Persons

Arthritis Foundation

Consumer Federation of America

Federation of Homemakers, Inc.

National Coalition of Hispanic Mental Health and Human Services Org.

National Consumers League

National Council of Negro Women

National Council of Senior Citizens, Inc.

National Council on the Aging, Inc.

National Urban League

Public Voice for Food and Health Policy

Public Citizen Litigation Group

Retired Persons Services, Inc. (Pharmacy)

U.S. Office of Consumer Affairs

Center for Science in the Public Interest

Consumers Union

Health Research Group

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American Academy of Family Physicians

Ms. Rosemarie Sweeney

American College of Physicians

Ms. Deborah Prout

United States Pharmacopeia

Dr. William Heller
Mr. Joseph Valentino

American Hospital Association

Dr. Tim Redman

American Pharmaceutical Association

Dr. John Schlegel
Ms. Glenna Crooks

National Medical Association

Association of Health Care Administrators

Association of Academic Health Centers

ORGANIZATIONS INVITED TO THE
COMMISSIONER'S MEETING WITH FOOD TRADE ASSOCIATIONS
TYLENOL TAMPERING

February 24, 1986
Commissioner's Conference Room

Food Marketing Institute
- Anne McGhee - Sr. Gov. Relations Representative
- David Richman - Director of Quality Assurance, Giant Food

National Association of Convenience Stores

National Association of Retail Grocers of the U.S.

National-American Wholesale Grocers' Association
- Gerald E. Peck - President

Association of General Merchandise Chains
- Edward T. Borda - President

American Retail Federation
- Lloyd Hackler - President

Cosmetic Toiletry & Fragrance Association

Grocery Manufacturers of America
- George W. Koch - President
- Sherwin Gardner - Vice-President, Science & Technology

Council for Responsible Nutrition
- J. B. Cordaro

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TYLENOL TAMPERING

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American Society for Hospital Pharmacists
- Linda Harteker - Director of Public Information

American Pharmaceutical Association
- Glenna Crooks - Director, Policy Division

Private Label Manufacturers Association
- David Eldredge - Research Director

Proprietary Association
- R. William Soller, Ph.D. - Vice-President, Scientific Affairs
- Edwin C. Mulcahy - Assoc. General Counsel

Generic Pharmaceutical Industry Association

National Association of Pharmaceutical Manufacturers
- George Schwartz - Executive Director
- Niles Barry - President

National Wholesale Druggists Association

Aspirin Foundation of America

ORGANIZATIONS INVITED TO THE

COMMISSIONER'S MEETING WITH STATE AND LOCAL HEALTH OFFICIALS

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2:30
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    Pennsylvania Dept. of Health

National Association of Boards of Pharmacy
    David R. Work
    Executive Director
    North Carolina Board of Pharmacy

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Senator KENNEDY. In the course of these hearings, was there any variation about the degree of security or safety in different packaging of various products; for example, the plastic top on this one that is sealed versus the can product? Were there any recommendations to you that some particular packaging processes and systems were safer than others?

If so, what were the observations that were made?

Dr. YOUNG. I have with me a wide variety of these in my two briefcases. I passed these around and we discussed them in depth with consumers and others, and we looked at the pluses and minuses of each of them.

We were able to demonstrate very clearly that each of these, with a degree of dedication, could be invaded. The consumers, in looking at it——

Senator KENNEDY. Well, would there be more difficulty in some areas and less difficulty in others? Did you reach any conclusion that there were, maybe, one or two different types that were more particularly difficult to tamper with?

Dr. YOUNG. I will completely provide the minutes for you, as I mentioned earlier. As we looked at it, there were none in particular that were absolutely safe.

Ironically, we judged that the Tylenol packaging was at the very, very high end of the scale and that was the one that we had the tragedy with.

Senator KENNEDY. Well, that is commendable for the company and I think people ought to know that; but did the groups that you met with or you draw any conclusions that some were more safe then others even though they could be tampered with?

Dr. YOUNG. No.

Senator KENNEDY. You did not.

Dr. YOUNG. All of them could be tampered with.

Senator KENNEDY. That is right, but there was an equal degree. As I understand your testimony now, because I asked whether some were more safe than others, your response is that all could be tampered with.

My question is: Are some safer than others? I gather from your testimony that you said that the whole range of film wrappers, blister-strip packs, bubble packs, shrink-seal bands, foil papers and plastic pouches, bottle seals, tape seals, breakable packs, sealed tubes, sealed cartons, aerosol containers—the whole range that is available as safety measures—are equal in terms of the safety that they provide for the consumer.

Dr. YOUNG. Senator, I misunderstood your question as you first asked it.

Senator KENNEDY. OK.

Dr. YOUNG. I was answering that all could be tampered with.

Senator KENNEDY. That is right.

Dr. YOUNG. The State and local officials particularly asked for a study as to whether we could get a range to particularly come to grips with that. Actually, it is of interest that some people felt that the metal can, which you have an example of, was one of the easier ones to tamper with.

Senator KENNEDY. So you did have a variation?

Dr. YOUNG. Yes.

Senator KENNEDY. Now we know that the can is more easy to tamper with. Tell us the ones that are on the top since you obviously have done some evaluating.

Dr. YOUNG. Senator, may I say this, please. I would be delighted to meet with you in private to——

Senator KENNEDY. No; this is public.

Dr. YOUNG [continuing]. Discuss that.

Senator KENNEDY. This is the way we work up here, as you well know.

If you say that there are marginal differences in each, but you make a basic conclusion that they all are equally tamperable, then that answers the question.

Dr. YOUNG. There is a range——

Senator KENNEDY. That is what I was trying to get at several minutes ago.

Dr. YOUNG [continuing]. Of tamper-resistant packaging. However, because I do not want to give a catalog of these, broadly, to facilitate tampering, I would prefer to discuss the particular range in private, other than to say the Tylenol package is at the very high end.

Senator KENNEDY. And you are satisfied that in the consideration of the range the various industries are using the state of the art in the safest product?

Dr. YOUNG. We have seen, since 1983, a progressive increase in these; for example, the one that I cited, the metal cap. The state of the art is being followed with a degree of precision and evolutionary change that I think is important.

Senator KENNEDY. Well, I am not sure that answers the question.

As the principal guardian of the public in terms of the use of the various over-the-counter and prescription drugs which are available, can you give the assurances to the American people that the principal manufacturers across this country are using the state of the art in safety devices to protect the consumer?

Dr. YOUNG. Although I don't want to give false hope on tamperproof, the current state of the art is being used across the board.

Senator KENNEDY. Across the board by all of the manufacturers, and there are no additional recommendations that you would make to the companies across this country to provide additional safety for the consumer.

Dr. YOUNG. Senator, we are just in the phase now of studying that. I am completely evaluating it.

But, at this moment, I have not received advice to make wholesale changes.

Senator KENNEDY. All right.

You have started your study. When do you think you intend to conclude it?

Dr. YOUNG. I intend to conclude the study within 2 to 4 weeks.

Senator KENNEDY. Would you make that available to the committee?

Dr. YOUNG. Absolutely.

Senator **Kennedy**. Could I ask the Chair to make that available to the committee?

The **Chairman**. Sure.

Senator **Kennedy**. OK.

Could I ask, Mr. O'Hara, on February 18, an FBI spokesman said, "The Bureau's examination of the Tylenol bottles from Westchester County found no evidence of tampering so far," and the the spokesman went on to say that "The lack of evidence does not mean that tampering did not occur."

I understand that the FBI also furnished a written report to the Westchester County district attorney indicating there was no evidence of tampering. Then, 2 days ago, the FBI announced that "Previously undetected signs of tampering have now been discovered using sophisticated scientific examinations. Those examinations further determined," according to the statement, "That it was possible to invade the bottles after packaging was complete without detection through conventional means of examination."

That seems to be reversal of the earlier findings 'What can you tell us about both sets of tests that were done and the results of the testing?

Mr. O'Hara. On the initial test, Senator, I believe that it was meant to mean that at the time the initial tests were conducted we could not find evidence of tampering: the examination did not discover that.

As they progressed in the examination process and used different forensic methods, we came up with evidence of tampering. As soon as we discovered that, we went back to FDA and those involved to let them know that we had, in fact, discovered the tampering.

Senator **Kennedy**. It was within a sort of a week period.

Mr. O'Hara. Yes.

Senator **Kennedy**. You have been looking into this for some time, since the 1982, then within a week period you drew conclusions one way, and then a week later drew conclusions going a different way.

I am just trying to understand in terms of the public's interest and the protection of the consumer either what the tests were or what answers did you learn in the second test that you did not learn in the first one, and why?

Mr. O'Hara. Well, they only way I can answer that, Senator, is that it was more of an open-ended statement at first, that we had not detected evidence of tampering. We did not say they had not been tampered with.

Then the other exams, as I mentioned, did find the evidence.

Senator **Kennedy**. Evidently you used a different test, different criteria.

Mr. O'Hara. Yes, sir; we did. This is something that we are relatively new at, looking at this type of product: tampering with the product and evaluating it.

Senator **Kennedy**. Is there anything that you can tell us in terms of the types of tests that were used that would not be prejudicial to the investigation? None of us are interested in that, but it does seem to me that just in terms of the consumers' interests on this that anything you can tell us about the types of tests would be valuable.

Mr. O'Hara. Not being a scientist, Senator, all I can say is it was a high-resolution microscopic examination which resulted in the final analysis that the product had been tampered with, which detected the evidence of tampering.

Senator Kennedy. And that had not been done previously?

Mr. O'Hara. Well, I cannot tell you, sir. I am sure that they did what they could and then they continued their research to see better ways of doing what they had tried to do the first time through.

Our lab is not one to jump to conclusions and they certainly want to preserve their integrity of testimony and being able to document and back up what they say as a statement.

Senator Kennedy. I think all of us respect that about the Bureau. I suppose that the question in people's minds is they must have had that policy when they issued the release on the 18th, as well, and then they changed after.

Mr. O'Hara. But all we said is that we had not detected the evidence of tampering, Senator.

Senator Kennedy. Ms. Dawson, has the Poison Prevention Packaging Act accomplished what it was intended to do?

Ms. Dawson. I believe there is a widespread view that the PPPA has been quite effective in reducing the number of deaths as a result of ingestions by children.

Senator Kennedy. Can you give us some idea about the reduction of deaths or accidents to children over the period of recent years, or would you like to supply that for the record?

Ms. Dawson. I could supply that for the record. I could ask my associate here, Mr. Gidding, to tell you about that.

Senator Kennedy. Just briefly, some indication. I think it is important that parents know about what is happening in terms of the protection of their children.

If you have good news for us, we could use it at this hearing.

Mr. Gidding. Well, Senator, I am reluctant to give you hard statistics because this hearing is, of course, on the Tylenol contamination problem.

Senator Kennedy. Right.

Mr. Gidding. I think aspirin is probably the most dramatic example of the success of the PPPA. When we first got into the business in 1972, aspirin was ranked among the leading causes of accidental childhood death.

While I don't have an exact percentage, I am fairly confident that death percentage has dropped over 50 percent, at least.

In addition, I think we can also submit——

Senator Kennedy. Are we talking about tens of lives or hundreds of lives?

Mr. Gidding. I would have to submit that for the record.

Senator Kennedy. OK.

[Information supplied follows:]

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

INGESTION AND DEATH DATA RELATING TO THE EFFECTIVENESS OF PPPA REGULATIONS

Reductions in ingestions of regulated product categories are measured against 1982 data from the National Clearinghouse for Poison Control Centers (FDA). Although ingestion data from this source exist for the years 1983 and 1984, significant reductions in reporting as a consequence of budget constraints preclude the calculation of meaningful comparisons. The Commission is currently contracting with the American Association of Poison Control Centers as an alternate source of child ingestion data.

The last year for which death data are available is 1983. With the exception of aspirin deaths, the coding system for these data does not permit a breakdown by regulated product category. Deaths due to all household chemicals, which would include all regulated product categories, are tabulated and show a significant reduction since 1972.

POISON PREVENTION PACKAGING ACT

The Division of Poison Surveillance and Epidemiology within the Food and Drug Administration receives reports from approximately 400 poison control centers across the country. It is important to note, however, that these centers report on a voluntary basis, and that not all centers in the U.S.A. report to FDA. In addition not all cases of accidental ingestion are reported to poison control centers, but may be reported to emergency rooms in hospitals, to private physicians, or handled at home without professional help.

In trying to evaluate the effectiveness of regulations under the Poison Prevention Packaging Act, the Commission compares the number of ingestions reported for that category of regulated products during the year in which the regulation first became effective with those reported during subsequent years. Since it would be a monumental task to identify every individual product which contain the regulated substance, the Commission has selected a number of brand names to represent each regulated category, and these brands have been kept constant over the years. Although the data from this analysis do not give total numbers of cases occurring nationwide, it is hopefully representative and useful for identifying trends over the years.

A COMPARISON OF THE NUMBER OF INGESTIONS OF REGULATED SUBSTANCES BY CHILDREN UNDER 5

NUMBER OF INGESTIONS OF REGULATED SUBSTANCES BY CHILDREN UNDER 5
A COMPARISON OF THE EFFECTIVE YEAR AND 1982

Regulated Substance	Effective Year	Ingestions during the Effective Yr	Ingestions during 1982	Decrease since Effective Yr
Aspirin	1972	8146	1753	78%
Controlled drugs	1972	1810	541	70%
Methyl salicylate	1972	161	49	70%
Furniture polishes	1972	697	229	67%
Illumunating & kindling preps.	1973	1736	452	74%
Turpentine	1973	777	110	86%
Lye Preparations	1973	508	69	86%
Sulfuric acid*	1973	7	1	86%
Methanol*	1973	37	21	44%
Prescription drugs (oral)	1974	4180	2251	46%
Ethylene glycol	1974	138	59	57%
Iron preparations	1977	359	163	55%
Paint solvents	1977	641	180	72%
Acetaminophen	1980	1511	1118	26%

*Since these figures are based on a few cases, the percent decrease may not be reliable.

The National Center for Health Statistics in Washington, D.C., receives mortality reports from all 50 states. These data show the number of deaths among children under 5 years of age involving all household products have declined over the past years. The Commission also examines the number of deaths resulting from the accidental ingestion of aspirin-containing products, since this was the first regulation passed under the Poison Prevention Packaging Act. At the time that the regulation was passed, aspirin products were the number one most frequently ingested product by young children.

DEATHS OF CHILDREN UNDER AGE 5 INVOLVING HOUSEHOLD PRODUCTS

Deaths due to all household chemicals			Deaths due to aspirin products		
Year	# Deaths	Decline since 1972	Year	# Deaths	Decline since 1972
1972	216	---	1972	46	---
1973	149	31%	1973	26	43%
1974	135	38%	1974	24	48%
1975	114	47%	1975	17	63%
1976	105	51%	1976	25	46%
1977	94	56%	1977	11	76%
1978	81	63%	1978	13	72%
1979	78	64%	1979	8	83%
1980	74	66%	1980	12	74%
1981	53	75%	1981	6	87%
1982	67	69%	1982	5	89%
1983	55	75%	1983	7	85%

(234)

Mr. GIDDING. In other areas besides death, which is not necessarily the most reliable measure of success, we have seen reductions in ingestions and injuries; we will furnish that for the record in the product categories we regulate.

Senator KENNEDY. Now, are we correct in assuming that most of the ingestions are now from household products rather than from the various tablets?

Mr. GIDDING. Well, there are a variety of products on the market. I think the single largest numbered ingestions of products for which we have established packaging requirements now is with prescription medications; however, that is also a function of the number of units sold and certain packaging conditions.

With respect to hazardous substances—for example, the drain cleaners and paint strippers—I don't believe they equal in volume the drug products that we also regulate; but, once again, we would pleased to submit that information for the record.

Senator KENNEDY. OK. Well, you get what I am driving at.

If we could draw some conclusions with regard to children's deaths or accidents with regard to ingestation as a result of the safety program, I think that would be of help.

Could you draw any conclusions in the Department about the sealing of capsules and whether they ought to be required?

Ms. DAWSON. I think I can respond to that. Our focus has been on the ability of the consumers to use the packages properly and not on the tamper-resistance or the technical assessment of the covert package entry.

Senator KENNEDY. I see. OK.

But clearly you have been very much involved in developing techniques to try to discourage children from abusing various household products and over-the-counter products——

Ms. DAWSON. That is true.

Senator KENNEDY [continuing]. And you have had some important success.

Ms. DAWSON. I think we have had.

Senator KENNEDY. As we move on into these tamperproofs, you are talking about the casual use of children and not the sophisticated tampering——

Ms. DAWSON. Not the deliberate.

Senator KENNEDY [continuing]. Which has resulted in these tragic deaths.

Ms. DAWSON. That is correct.

Senator KENNEDY. Therefore, that is where your focus is and you are not prepared to respond on the——

Very good. I thank you very much.

Ms. DAWSON. Thank you.

The Chairman. I understand Senator Metzenbaum does have some questions as soon as he can return.

Senator KENNEDY. Maybe until he comes back, could I ask Dr. Young a question?

What can you tell us about how tamperproof the tablets are?

Dr. YOUNG. There is no particular dosage form, Senator, that cannot be tampered with, as was mentioned earlier by Mr. Clare of Johnson & Johnson; and it is difficult to assess the quantitative nature by which they can be tampered.

It is important for me to stress for you, too, that counterfeiting occurs and one of the larger problems that we detected this year was counterfeiting of Ovulen, which was not even detected by pharmacists and was only first found by consumers.

So that it is important for consumers to look at the medicine carefully that they take.

Senator **Kennedy**. Is the prescription drug supply safer, do you believe?

Dr. **Young**. We have had no incidence of tampering with the prescription drug supply, but the distribution chain would be similarly vulnerable in prescription as it is in over the counter.

Senator **Kennedy**. Would you draw, then, the conclusion—or should consumers—that in terms of the prescription drugs there is even a higher degree of safety and security?

Dr. **Young**. Yes; I would say so.

Senator **Kennedy**. Is that a fair conclusion for people to draw?

Dr. **Young**. Yes; I would say it is. I believe it is possible to deal with the distribution chain, though.

Senator **Kennedy**. I think that is important.

Thank you.

The Chairman. Thank you, Senator.

Senator Metzenbaum.

Senator **Metzenbaum**. Dr. Young, can you tell us how the tampering occurred? Was it by pulling the capsule apart and substituting the cyanide? Is that the procedure that was used?

Dr. **Young**. To the best of our knowledge, that was the procedure that was used and there were a few clues.

First, the capsule almost completely contained cyanide with very little acetaminophen; and, second, the capsule was not realigned properly. When the capsule is manufactured, most of the times the label on the two sides of the capsule align and this was off alignment.

Senator **Metzenbaum**. Cyanide comes in liquid form as well as in solid form?

Dr. **Young**. You can put it into a liquid form, but it is usually solid.

Senator **Metzenbaum**. One of my concerns is that no matter how you slice it if the individual is determined enough that you can tamper with the pharmaceuticals or food, or whatever the case may be.

Dr. **Young**. You are absolutely correct, Senator. I am particularly pleased that you reemphasize that because that is the core of the problem.

Senator **Metzenbaum**. Let me ask you a question. It is a little capsule. You can use sonic-sealing or any 1 of 10 other different ways of sealing the capsule.

Is it possible to use an injection needle to put the cyanide or some other poison in and then reseal the hole?

Dr. **Young**. I would be delighted to discuss that with you in private, sir; but I feel that it would not be an appropriate answer for me to give now.

Senator **Metzenbaum**. I think that is fair. I appreciate that.

It just seems, as I sit here, that there are so many ways that tampering can occur—and that is not my business, obviously—it just seems to me that Johnson & Johnson took a major step in removing their product from the market. Yet, as I think about it, I have the feeling that if there is a will there is a way to tamper with pharmaceuticals of food products in this country.

All we can hope is that there are not that many wackos, crazies or actual criminals—terrorists, whatever—who make up their mind to do so.

Dr. **Young**. Yes. History is replete with examples of individuals that have chosen to use different forms of poisoning. In fact, I went back and reviewed this Socrates' death with a particular type of poison was one of the earlier documented cases.

Senator **Kennedy**. Ivan the Great poisoned seven of his wives. [Laughter.]

Dr. **Young**. There are many examples.

Senator **Kennedy**. Or Ivan the Terrible, rather. [Laughter.]

Dr. **Young**. I was not going to correct you, either. One man's great is another man's terrible. [Laughter.]

I served for a short period of time, when I was a pathologist, as a coroner in Cleveland, OH, or did coroner's cases at Western Reserve. The most usual one was "You went out with my wife," bang, bang, bang in one form or another.

Ivan's problem was symptomatic of what occurs quite frequently. [Laughter.]

Senator **Metzenbaum**. On that note, I think I have no further questions.

The **Chairman**. I want to thank all five of you for appearing. We appreciate having you here.

This is an important hearing and we are trying to get to the bottom of what might be done.

Dr. **Young**. Thank you very much for having us, Senator. If we can help in any way at any time, please do not hesitate to call upon us.

The **Chairman**. Thank you so much. We appreciate it.

We will now call Dr. Arthur Hull Hayes, dean and provost of the New York Medical College, former Commissioner of the Food and Drug Administration.

Dr. Hayes, we welcome you to the committee once again. It is awfully good to see you. We hope everything is going well with you up there at the New York Medical College.

We are pleased to turn the time over to you.

STATEMENT OF DR. ARTHUR HULL HAYES, JR., UNIVERSITY PROVOST, NEW YORK MEDICAL COLLEGE; FORMER COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION

Dr. **Hayes**. Thank you very much, Mr. Chairman. Good morning, and good morning to the members of the committee.

I am Arthur Hull Hayes, Jr., university provost of New York Medical College. I am a physician, internist, and clinical pharmacologist by training and scientific activity. I was Commissioner of Food and Drugs from April 1981 until September 1983; a tenure which included the time of the first Tylenol tragedy in the fall of 1982.

I might mention the fortuitous circumstance that I am a Westchester County resident of the town next to Bronxville.

I am pleased to accept your invitation, Mr. Chairman, to appear before this committee once again although in an obviously different capacity and under the most unpleasant circumstances which have prompted the convening of this hearing.

I must also say that it's a bit lonelier up here at the table than it used to be.

Because of the short notice of the invitation and the fact that I am literally between offices as we move our administrative headquarters on the university campus, I do not have a prepared text to give you, but will be very happy to supply a transcript after the hearing if that will be helpful.

The CHAIRMAN. If you do that, we will be very happy to make it part of the record.

Dr. HAYES. Thank you, sir.

My remarks are brief, but I hope they will be contributory to this hearing.

My memories of the Tylenol tampering of 1982 need no refreshing; they are really quite vivid even to this day.

They were very long days for many of us at the FDA, in the industry, amongst health professionals, and certainly amongst consumers. They were days of uncertainty, of fear, of concern, and even, at times, of anger.

But they were, I believe the record shows, days of intense effort and of discussion, of decision and of productive action. Although then it was a new phenomenon, the Food and Drug Administration, Johnson & Johnson, the Proprietary Association and others in the over-the-counter industry responded to what was, in fact for well over a fortnight that fall of 1982, a very fast-changing situation.

Nothing then seemed simple and straightforward because, in fact, nothing was simple and straightforward. The events and the potential responses were complicated and often uncertain from hour to hour and day to day.

As we in medicine are sometimes wont to say, only through the proverbial retrospectoscope may it seem simple and straightforward today.

Eight murders, which, by circumstance, were tantamount to terrorism, had occurred and the public and the availability of their over-the-counter medicines—and by simple and logical extension other consumer goods—were threatened. Individuals had died from cyanide in Tylenol, poison in medicine: clearly an incredible marriage of ingredients.

This was done deliberately without warning or discernible reasons.

Other apparent tampering events, as you will recall, which were coincidental but perhaps related through some psychological mode, only cast further shadows of doubt and uncertainty at that time.

Much was done—and I believe it was done well and done quickly—by many. At FDA, as you know, we organized a headquarters task force; our field representatives were in retail outlets; our scientists burnt the midnight oil in the laboratories, examining within a fortnight some million and a half capsules.

The FDA and the Proprietary Association organized and convened a technical committee; and, as you also know, regulations relevant to tamper-resistant packaging were on the books in what I think is still a record for the Food and Drug Administration.

Caution and reassurance, where justified, were brought to the public via the media. While at the time my children thought it was glamorous to be on morning and evening network television, we literally did not know sometimes when we went on the air what the latest set of events were, much less their interpretation.

Tamper-resistant packaging was introduced, a concept that quickly became a fact. Education of the public, as well as reassurance—as Dr. Young has said—was seen to be important and was fostered through responsible media reporting as well as through public service announcements.

I must tell you that, in looking back on the fall of 1982, there was no time during my tenure that I was more proud to be Commissioner, and believe that the encomia which the FDA subsequently received from the President of the United States, HHS Secretary Richard Schweiker, the Congress, the health professionals, industry, the media, and especially the public whom FDA is charged to serve, were very well deserved.

Industry did a good job. With rare exceptions, media was responsible. It was a good record; and, indeed, since then, as you have heard earlier today, the record with respect to tampering is a rather good one. Considering the number of capsules, the number of over-the-counter medications, the number of accessible consumer products and the record on tampering, it really is very good indeed.

As I reflect on 1982, I think a fair question is: What did we learn that might help us to address this second episode—or number of episodes, perhaps—which is both new and different?

First, I believe we learned that over-the-counter medications and many consumer products are vulnerable, but can be made less so by tamper-resistant packaging, appropriate labels and warnings, and effective education.

Second, we certainly learned—and it has been said many times since—that there is no absolutely safe product. Nothing is absolutely tamper-resistant.

The human mind, even if evil or deranged, can be clever, ingenious and determined; and, indeed, in the present case of Tylenol tampering, it took, I understand, scanning electron microscopy to show that tampering had occurred. It was not many years ago when that diagnostic test would not even have been available.

We realize that many consumer goods are accessible to the public, including over-the-counter drugs and common chemicals, because the public, through a series of decisions over the years, wants them that way. In fact, many of us in both the private and public sectors capitalize on this availability and accessibility, not only with advertising but with education.

How many times have we told the public: Read the label. Look at the micro and macro ingredients. Look at the indications for the drug, the cautions. See how much cholesterol there is. Think about sodium or calcium or potassium with your hypertension. And on and on.

We urge customers to compare packages and prices and labeling and convenience. In short, I believe we learned that people want and have come to expect to be able, with respect to consumer products and certainly over-the-counter drugs, to look, to read, to examine, to compare, and maybe even to squeeze.

Thus, I believe that before we significantly alter or devastate or even destroy this system we should consider carefully the consequences. It is not and cannot be a question of something for nothing. There is no such thing as risk-free, at no cost, with no change in what we want and expect.

If reaction to a particular type of tampering is to remove or to ban that which has been or could be tampered with, then in fact it is the tamperer—real or potential—who is in control. No good purpose is served now to enumerate or elaborate the details of this road; indeed, I think that it would be only tempting, if not demonstrative, to other would-be tamperers.

But is a long road and it is literally endless. The only result, I believe, that is predictable is that it would be a different world and not the open and free society with accessible products that we now have.

I would like to be clear about one thing, Mr. Chairman. I am not here today representing anyone but myself and I am not selling anything; I am not advocating or decrying any particular action; and I will not speak, must less recommend, outside my present knowledge, experience or competence about what specifically can and should be done.

I don't know if any particular dose form—capsules of whatever form, liquids, and others ad infinitum—is necessary, helpful or, in fact, preferable to the consumer, and at what cost or risk and with what substitute. I think there is no question, as has been said, that a tablet is harder to tamper with than a capsule.

I also remind the committee that the package of Tylenol which was tampered several weeks ago was very much harder to penetrate and penetrate successfully than was the package of some 3½ years ago.

So it is a question of degree rather than it can or it cannot, or it will or it will not.

I also don't know how tough cellophane can be made. I don't know how impenetrable a carton's glue joint can be fashioned. I don't know how irreplaceable, without detection, an aluminum seal can be designed.

Pharmaceutical science and clinical need should address the former, and technology and latter; and all of these should be encouraged and, indeed, pushed to the limit by all appropriate means of persuasion and increasing motivation.

It has been suggested that over-the-counter drugs, or at least some of them, should be behind the counter. I point out to you that in countries where, in fact, this is the case it has been shown not to be foolproof, and one has to define very carefully what one means by "behind the counter": who, in fact, has access to it. As we know, even prescription drugs may sit in the drawer, with a number of clerks passing by every day, for some 48 or 72 hours before picked up by a consumer.

I do not believe that there are any quick fixes. I do not believe that there is any remedial action without some cost: of availability, of convenience, of money, sometimes even of possibility.

I would be gravely concerned if a knee-jerk reaction of apparent benefit resulted in losing our freedom to compare and scrutinize and to choose consumer products without a real, lasting, demonstrable benefit. In such a circumstance, those would be, in effect, traded for at least one new worry that we have not considered, well-said by the Latin author: "Quis custodiet, custodies?" "Who is watching the guards?"

I believe that FDA, industry, the health professionals, Congress and especially the consumer—all from different perspectives, to be sure—want the greatest safety from tampering with access and availability of consumer products. They, not the malicious and deranged, should decide what is available in what form and at what risk.

If they hold the power of decision, they may not be infallible but I know them, because you and I are among them.

I don't know and I don't understand the tamperer, and I certainly don't trust him.

I read in the press the other day in a discussion of the most recent Tylenol episode, about who is wearing the white hats and who is wearing the black hats, and who is giving them out. Quite frankly, Mr. Chairman, I think we know who is wearing the black hat even if his identity has not yet been revealed.

I think the real issue is the conduct of those who are wearing hats that I suspect are of many different colors but at least have a white lining inside.

Mr. Chairman, as I used to say, that concludes my testimony; but I will be very happy to attempt to address any questions you or members of the committee may have.

The CHAIRMAN. Thank you. You gave a particularly articulate statement.

I think one thing this hearing is showing is that there have been a lot of strides made in industry to protect the consumers since 1982. In these intervening 3 years, there have been remarkable changes and some very successful protections, and the incidents have come down. We are all very happy for that.

One of the purposes of this hearing is to see if there is anything more we can do. Do you have any additional suggestions as to what might be done to resolve these problems?

Dr. HAYES. I don't know how to go about solving crime even though we all like to have theories and be at least amateur detectives. I think, perhaps, there are some things that could be done, if the technology exists, that would make certain dose forms and certain packaging more tamper-resistant, recognizing that one is talking about gradations. We have also seen one of the most tamper-resistant products apparently successfully violated.

I think also, Mr. Chairman, that we have to appreciate that history, in this case, is not repeating itself—that we start from a different base—and that as new challenges arise in this, as in so many areas, then one must respond to them.

One cannot infer from that that one ought to guess what the challenge will be or the successful tampering and by whatever means, and then work to circumvent it. I do believe, as I said earlier, that every persuasive power should be used: That the technology, the pharmaceutical chemistry, and the clinical need, which is important here, should be assessed and pushed to the limit so that the consumer product accessibility which we have come to enjoy and, indeed, rely upon, will not be compromised and yet the safety will be the best that we can make it, recognizing that best may never be good enough.

The **Chairman**. Thank you.

Senator Kennedy.

Senator **Kennedy**. Thank you, Dr. Hayes.

I noticed in your testimony you said that the capsules are more easy to tamper with than the tablet.

Dr. **Hayes**. I am saying that, quite frankly, Senator, on the basis of what those who are pharmaceutical chemists and organic chemists tell me in terms of what will degradate, what will change color and the like; and it seems reasonable.

But I cannot give you the data.

Senator **Kennedy**. But if that were so, then should the FDA consider banning the capsules and require tablet form?

Dr. **Hayes**. If there is no adequate reason for capsules and as they have been shown to be tamperable, then I don't think there is any reason for capsules; and, quite frankly, I would be surprised that manufacturers would try to sell them because I don't think consumers would want them.

I do not know and it is outside my competence as to whether there are medications that cannot, with present technology, be formulated otherwise because it would destroy the medicine, render it inactive, more toxic or what not; or to what degree the convenience of swallowing or time-release in terms of pharmacokinetics are unique to capsule formulation as against others.

I just cannot answer that.

Senator **Kennedy**. We have to listen—obviously we are not experts in that—but if you were satisfied that in terms of the medicinal consideration that they were virtually equal, would you feel then that an additional element of safety would be achieved by having the tablets rather than capsules?

Dr. **Hayes**. No question about it; and I would think that of any dose form under similar circumstances.

Senator **Kennedy**. You say there is no question about it.

Dr. **Hayes**. No; there is no question. If you don't need something and you know that it can cause harm, then there is no reason to have it. What remains, as you have said, is whether, in fact, capsules serve a legitimate purpose; and, if so, then how can we, A, look for alternatives in the future from a technological and pharmaceutical standpoint and, B, how can we make them, while we must use them, as safe as possible?

Senator **Kennedy**. Well, the testimony that we heard is that the tablets can also be tampered with. Clearly the judgment of Johnson & Johnson has been to move toward a tablet form; but we know that the capsules are used by many other manufacturers.

As you pointed out in your testimony, there are different balances—cause, convenience and other factors—but I suppose that we have to measure the safety implications in this as well.

I gather from what you said—you conducted the review after 1982—you believe that if the time-release aspects can be made equal in tablets as well as in capsules and other factors in terms of the medicinal implications of these medicines, then we would be wise to give consideration to moving toward tablets completely and away from capsules; and that that ought to be something the FDA takes a hard look at.

Dr. HAYES. I would be surprised if they are not already giving it a hard look as I cannot believe those in industry are not.

Senator KENNEDY. I did not gather that from Dr. Young's testimony, but they did indicate that he was going to do a more comprehensive review and report to the committee. I would certainly hope that we would have the opportunity to raise that particular issue with him.

When you were in the FDA, during your review of the 1982 tragedies, did you consider abandoning the over-the-counter capsule products?

Dr. HAYES. Well, if by consider you mean did we discuss it, yes, we discussed just about every option that I can even, to this day, think of.

Senator KENNEDY. What can you tell us about that discussion.

Dr. HAYES. At that time, we were persuaded that capsules had legitimate place on the market. I cannot speak to how technology has changed.

You suggested that anything you can do with respect to time-release and the resulting pharmacokinetics with capsules can be done with tablets. My knowledge of pharmacokinetics suggests that may be true, but has not been demonstrated.

So that, at that time, we were persuaded——

Senator KENNEDY. Well, I gather that we ought to at least pursue that.

Dr. HAYES. No question.

Senator KENNEDY. If it may be true and has not been demonstrated, and you believe as a former authority in this area that there are additional kinds of safety aspects built into the tablet, that that certainly ought to be one area of important review in terms of the safety.

Dr. HAYES. No question about it, but, in 1982—in direct response to your question—we were persuaded, and I believe could demonstrate, that if all capsules were removed there would be a significant disadvantage to the consumer.

Senator KENNEDY. The FDA regulations, as I understand them, require that a seal be put on the container. There are many products that come out in which many companies have gone far beyond that in terms of trying to protect the interests of the consumer.

Do you think it ought to go beyond just providing a seal, the requirements that just a seal be put on the container?

Dr. HAYES. Well, I am not sure I am the one, really, to give a definitive or data-based answer to that. I think that, certainly, one could argue that for certain products some kinds of seals may not provide as much protection as if the seal were different, or if there were more seals or if as in the case of Tylenol there were, in fact, three different barriers including the package itself.

I think there is no question that one wants to look, within the bounds of reason and, quite frankly, cost and availability to consumers, at the safest packaging possible. It is also true that no matter how many padlocks were put on the safe, Houdini still got out.

Senator KENNEDY. I don't know whether you have any impression or whether, from your past experience and current knowledge, you are satisfied that the state of the art is being used by all the manufacturers now in terms of protections for the consumer.

Dr. HAYES. Quite frankly, Senator, I have not done a survey of what is out there. I am trying to keep a medical school in the black and moving forward with all that is going on in health care.

I must confess that I have seen packages that I think are more tamper-resistant than others; but whether that is a difference between 100 and 50 or 100 and 99½, I am not prepared to say.

Senator KENNEDY. But you would agree that that ought to certainly be something that has the ongoing and continued review and involvement, I imagine, of the FDA and also with respect to the industry.

Dr. HAYES. By both; absolutely.

Senator KENNEDY. You had an industrywide kind of a group that advised you, did you, in 1982?

Dr. HAYES. In 1982, the Proprietary Association—from whom I understand you will hear later—and the Food and Drug Administration set up a joint technical committee. This was to look at the technology and the state of the art, and where it might go with respect to packaging.

Senator KENNEDY. Was that helpful to you?

Dr. HAYES. Very helpful, indeed.

Senator KENNEDY. I understand it has just been reconstituted.

Dr. HAYES. That is correct, sir.

Senator KENNEDY. I think that is certainly encouraging. We will look forward to gaining whatever information we can from them, as well.

Thank you very much.

The CHAIRMAN. Thank you, Dr. Hayes. We appreciate having you here and the effort you have made to be here.

Dr. HAYES. Good to be back, Mr. Chairman. Thank you.

The CHAIRMAN. Glad to see you again.

Let's now turn to our fourth panel, which will be Ms. Nancy Harvey Steorts, president, Nancy Steorts and Associates, former Chairman of the Consumer Products Safety Commission; Dr. Monroe Gilmour with the American Association of Retired Persons who will be accompanied by Ms. Judith Brown, also of the same organization; and Ms. Odonna Mathews, vice president, Consumer Affairs of Giant Food Corp.

I am going to have to limit each of you to 5 minutes, I hope you will not mind, but we will put your full statements into the record as though fully delivered. We welcome you to the committee and appreciate having you all here and the efforts you have put forth. Ms. Steorts?

STATEMENTS OF NANCY H. STEORTS, PRESIDENT, NANCY STEORTS AND ASSOCIATES, FORMER CHAIRMAN, U.S. CONSUMER PRODUCT SAFETY COMMISSION; DR. MONROE GILMOUR, MEMBER OF THE BOARD OF DIRECTORS, AMERICAN ASSOCIATION OF RETIRED PERSONS, ACCOMPANIED BY JUDITH BROWN, OF STAFF; AND ODONNA MATHEWS, VICE PRESIDENT, CONSUMER AFFAIRS, GIANT FOOD CORP

Ms. STEORTS. Mr. Chairman and distinguished members of the Senate Committee on Labor and Human Resources, I am delighted to be back in Washington and thank you very much for inviting me. I will shorten my statement and I appreciate it being put into the record.

The CHAIRMAN. Without objection, it will be done.

Ms. STEORTS. I applaud your foresight in having this oversight hearing which focuses on the health and safety of the American consumer. As Chairman of the Consumer Products Safety Commission during the first term of the Reagan administration, I feel CPSC with a very able Commission staff developed programs which were beneficial to the individual consumer of our Nation and resulted truly in a safer marketplace.

Consumers today are truly concerned about the safety, the safety of all products: Food, cosmetics, drugs, automobiles, airplanes, just to name a few of the product categories. Right now, however, I feel consumer consciousness is especially focused on the safety of our Space Shuttle and on protection against tampering with the over-the-counter manufactured goods.

Where does the corporate responsibility begin and end? What, in fact, is the consumer's responsibility? Last, but certainly not least, what is the responsibility of Government today?

Deregulation has brought about many pluses, but also some very serious minuses. During my tenure as Chairman of the Commission, we worked closely with industry on the development of standards to protect and benefit the consumers, and ultimately in my opinion the manufacturer as well. Unsafe products cannot and should not be in the marketplace.

Again, while I was Chairman, we say many different industries with many different problems. Some manufacturers fought removal or corrective action programs and spent thousands of dollars in costly legal fees to try to disprove adverse judgments and to avoid penalizing actions. Some were less overt. They denied responsibility and, so to speak, dragged their feet.

Then there were a few role models from industry who, without a doubt, had the interest and concern of the consumer as a No. 1 priority. Even with the latter, everything is not going to be perfect.

There are times in any company's history when the best-intentioned manufacturing process has turned out a flawed product. There are times when expected consumer use changes and thus unexpected problems and crises arises.

There are also, as we see today, societal changes that can bring different circumstances and problems to the marketplace. Consumers, industry, and Government must address these significant changes.

Today, we are plagued with new problems and we live in a very changing environment. We must respond to these changes in a reasonable and rational way.

Over the past few weeks, consumers have once again been threatened and frightened by tampering with consumer products. Rationally, we all know that we cannot live in that isolated bubble, safe from the intrusions of such mindless behavior. Such would be a unrealistic approach.

On the other hand, consumer fears are real: One headache, one over-the-counter remedy, one death. How sad, how tragic: Tragic for the victim, the family, the manufacturer, the retailer and the free enterprise over-the-counter system.

It is important, however, to examine how this most recent tragic scenario with Tylenol was handled. Johnson & Johnson, under the very competent leadership of Chairman James Burke, reacted expeditiously, effectively, and I believe very wisely.

Both when I was Chairman of the Commission and today as I serve as a private sector management consultant, I find this corporation stands as a leader and probably the industry role model. When Chairman Burke received the first notification of another potential problem, a possibly Tylenol-related death, he did not bury his head, pass the buck, go to the lawyers, close out the press, or have his subordinate face the consumer.

He, himself, took that responsibility; and I think it is extremely important to see what Johnson & Johnson did, and I hope that other companies when confronted with such a problem will follow the same suit.

The CHAIRMAN. Ms. Steorts, I appreciate your comments. We are going to put the rest of your statement in the record. It is an excellent statement.

[The prepared statements of Ms. Steorts follow:]

THIS TESTIMONY REPRESENTS THE PERSONAL VIEWS OF NANCY HARVEY STEORTS ONLY.

STATEMENT OF

NANCY HARVEY STEORTS
former Chairman,
U. S. Consumer Product Safety Commission

President, Nancy Harvey Steorts & Associates
Dallas, Texas

before the

United States Senate Committee
on Labor and Human Resources

UNITED STATES SENATE

February 28, 1986

Mr. Chairman and distinguished Members of the United States Senate Committee on Labor and Human Resources:

I applaud your foresight in having this oversight hearing which focuses on the health and safety of the American consumer. As Chairman of the Consumer Product Safety Commission during the first term of the Reagan Administration, I feel CPSC, with a very able Commission staff, developed programs which were beneficial to the individual consumer of our nation and resulted in a safer marketplace.

Consumers today are very concerned about safety -- the safety of all products -- food, cosmetics, drugs, automobiles, airplanes -- (to name just a few of the product categories). Right now consumer consciousness is especially focused on the safety of our space shuttle and on protection against tampering with over-the-counter, manufactured goods. Where does corporate responsibility begin and end? What in fact is the consumer's responsibility? And last but certainly not least, what is the responsiblity of government today?

Deregulation has brought about many pluses, but also some very serious minuses. During my tenure as Chairman of CPSC, we worked closely with industry on the development of standards to protect and benefit the consumer and ultimately, in my opinion, the manufacturer as well. Most of the standards improved during my Chairmanship were developed with the cooperation of the affected industry and were brought into being on a voluntary basis. I believe in the "carrot and stick approach" for a regulatory agency. The threat of potential regulation, for most industries, leads to their voluntary development of appropriate standards to ensure a safe product for the customer.

Unsafe products cannot and should not be in the marketplace. Under the Consumer Product Safety Act, any product that is deemed to be unsafe must be reported to the CPSC. The judgment is made after thorough investigation as to whether it will be recalled and/or banned. Some manufacturers fought removal or corrective action programs and spent thousands of dollars in costly legal fees to try to disprove adverse judgment and to avoid penalizing actions. Some were less overt; they denied responsibility and so-to speak dragged their feet. Then there were a few role models from industry who, without a doubt, had the interest and concern of their customers as a number one priority.

Even with the latter, everything is not going to be perfect. There are times in any company's history when the best intentioned manufacturing process has turned out a flawed product. There are times when expected consumer use changes and ,thus, unexpected problems and crises arise. There are, also, societal changes that can bring different circumstances and problems to the market-place. Consumers, industry, and government must address these significant changes. Not an easy task!

Today we are plagued with new problems and we live in a constantly changing environment -- we must respond to these changes in a reasonable and rational way.

Over the past few weeks, consumers have once again been threatened and frightened by tampering with consumer products.

Rationally, we all know that we cannot live in an isolated bubble -- safe from the intrusions of such mindless behavior. Such is an unrealistic approach.

On the other hand,our fears are real. One headache, one over-the-counter remedy, one death. How sad, how tragic! Tragic for the victim, the family, the manufacturer, the retailer, and the free enterprise, over-the-counter system.

Let us examine how this most recent tragic scenario with Tylenlol was handled. Johnson & Johnson, under the very competent leadership of Chairman James Burke, reacted expeditiously, effectively, and I believe very wisely. Both when I was Chairman of CPSC and today as a private sector management consultant, I find this corporation stands as a leader and the industry role model.

When Chairman Burke received the first notification of another potential problem -- a possible tylenol-related death -- he did not bury his head, pass the buck, go to the lawyers, close out the press, or have a subordinate face the consumer. Let us take a look at what I consider the crucial elements of Johnson & Johnson's responsible corporate behavior:

1.. There was no moment of paralysis; there was an immediate take-charge attitude.

2. Concern and attention to detail was at all times apparent. There was gathering of information to see all of the pieces as well the whole.

3. There was two-way communication between the press and the public. The communication has been continuous, welcomed -- responded to, and appreciated.

4. There was a single spokesman, and one from the top. Chairman of the Board, James Burke has been accessible and forthright; (the President David Clare was also available and in concert).

As a result J & J appeared united, strong, objective and personally compassionate. This is a corporation on the offensive not the defensive as they instigated their own investigations and cooperated with others. Their corporate objective was to maintain their company confidence -- in their own product and to restore public confidence. Their final decision to recall all of their capsules, to scrap their production, and in addition to create new emphasis and direction by promoting the elongated tablets called Caplets will cost J & J as much as $150 million. A small price however for credibility and future success. What was their alternative? Was this the right decision for the Johnson & Johnson Company? They thought so and consumers seem to agree. Should other companies follow suit? This is a tough decision and one that needs to be looked at realistically and individually.

We are now at a stage where, as consumers, we can no longer take our products for granted. We too have a responsibility. We must exert more care when purchasing products to be sure that they have not been tampered with -- we need to spend a little longer choosing medication today. We may need to make more choices at the drug counter. If we want a certain brand of medicine, we may not be able to obtain it in the form we have become accustomed to buying; a new consumer attitude may be necessary; there are new consumer choices that will have to be made.

What is the responsibility of government today? Government has the responsibility to serve as a catalyst -- to bring about greater awareness of new major consumer issues. Protecting the health and safety of the consumer is an essential function of the federal government. I feel strongly that the time has come for a total review of how the government is addressing these concerns. Is the consumer confused by the various safety agencies and the issues they address? Is the industry confused as to which agency addresses which products?

Just three short years ago, when Johnson & Johnson developed their tamper-resistant packaging through the Food and Drug Administration, it was found (after the new packaging was completed and marketed) that the tamper resistant packaging affected by 1/1000 of an inch the child resistant closures which came under the jurisdiction of the CPSC. Confusion! Confusion -- both for the manufacturer and for the consumer.

The time has come for a thorough review of the health and safety functions of the United States government. With budget constraints what they are and cut-backs being put into place, the time has come for a co-ordinated, well-focused health and safety agency which has total regulatory authority, not piece-meal as we have it today.

Mr. Chairman, the time has come to make some changes. A concerned consumer and a concerned industry would be better served if all health and safety functions were put under one agency. It seems most appropriate to review how this can be best accomplished. Thank you for the opportunity to appear before you. I will be pleased to answer any questions.

Nancy Harvey Steorts
2444 One Main Place
Dallas, Texas 75250

The CHAIRMAN. Let's turn to Dr. Gilmour.

Dr. GILMOUR. Good afternoon.

The CHAIRMAN. We are happy to have you here.

Dr. GILMOUR. I appreciate the opportunity of being here. I am a member of the board of directors of the American Association of Retired Persons and I, myself, am a retired physician.

We thank you for holding this very important hearing and appreciate the opportunity to be a part of it.

The American Association of Retired Persons represents 22 million older Americans above the age of 50. In other words, we are a good many consumers.

This age group consumes a disproportionately large amount of drug products sold both by prescription and over-the-counter. Although they account for only about 11.7 percent of the total population, older Americans consume 30 percent of the prescription drugs in this country. Per capita expenditures for over-the-counter drug products by older households are one-half to two-thirds greater than those of younger households.

AARP also operates the world's largest private mail service pharmacy which fills 7 million prescriptions a year.

We would like to commend the Food and Drug Administration for their quick and comprehensive actions surrounding the recent tragic tampering incidents: actions which you have already heard about in detail. Similarly, we would like to commend Johnson & Johnson for their bold actions to protect the public health and the public confidence, which is exceedingly important since fear can be such a devastating emotion.

The question of whether all over-the-counter capsule formulations ought to be banned seems to be hanging in the balance. AARP hopes that no such legislative or regulatory steps are taken to ban these products.

It seems clear that certain market forces will, and should be, allowed to prevail. This is one clear case where industry has a real incentive to do something and those interests are totally consistent with the public health interests.

We feel that to ban capsules "just to be doing something" would be a mistake. There are about 45 over-the-counter capsule products on the market. Some could readily be converted to caplets and some could not, like the sustained-release products. Some of my partners in the practice of medicine feel that they would be hampered in their medication use if they did not have certain of these capsules available.

To have FDA to spend their time and resources for regulations to deal with this problem seems futile in light of the nature of the crime. The FDA regulations on tamper-resistant packages after 1982 were comprehensive and successful in rendering greatly increased safety.

We are obviously not dealing now with casual tampering here. We are dealing with crime and with a demented, thwarted, devious mind that is hell-bent on contaminating medication. Our food supply, for that matter, is also vulnerable.

AARP previously voiced strong concerns that packaging changes not prove to be elder-proof and expressed the hope that manufacturers would take into consideration minimal levels of accessibility so that the older people could get at their medicines.

I asked one patient if she had any trouble opening her child-proof bottle. She said, no, she had no trouble: her grandson did it for her. [Laughter.]

Dr. GILMOUR. We feel that FDA resources, beyond what have already been expended, are better directed at continuing the present useful activities in public education about Reyes syndrome, completing the over-the-counter product review to get unsafe and ineffective drugs off the market, and better enforcement capabilities.

These are some examples of what would be more appropriate ways for the FDA to use their limited funds and personnel.

Certainly some effort is worth making, however. One that has been emphasized today and I would like to re-emphasize is that consumers need to be educated to look more closely, more carefully at what they buy.

The U.S. Pharmacopeia has produced a pamphlet, "Tips Against Tampering," which you just saw today. That should be more widely disseminated and perhaps made more simply understood.

We have to remember that 30 percent of our people are somewhat illiterate. Brochures do not necessarily tell them what to do about these things. We also need public service announcements and other things.

We are looking into AARP's Modern Maturity and News Bulletin for articles about tampering to help educate people. We have a circulation that is third in the country behind Reader's Digest and TV Guide. We hope other groups will also use their channels to spread information.

We are going to be offering an alternative to our own generic brand of Tylenol in a hard-shell pull-apart capsule. We will be selling our acetaminophen in a soft geletin capsule as well. We have noted that there are other means of protecting capsules such as those you have heard today like geletin banded seals by sonic or lazer procedures.

The response from our members to the recent tampering incident has been minimal. We have received very few comments at our 11 walk-in pharmacies across the country and no letters that we are aware of at our national headquarters.

Informal interviews with our members using the AARP pharmacy located at 1909 K Street, Washington, DC, have uncovered no alarm concerning capsules. Most we spoke to viewed it as an isolated incident and said they would continue to use over-the-counter capsules as they already do with so many of their prescription medicines.

We feel that if there was widespread concern among the 22 million people who are members of the AARP, we would be hearing about it.

In summary, the AARP commends the actions already taken to address the tampering incidents, commends your hearing today, and hopes that future steps will not prove to be an over-reaction to a very serious problem.

Thank you.

The CHAIRMAN. Thank you so much, Dr. Gilmour.

[The prepared statement of Dr. Gilmour follows:]

AARP

TESTIMONY OF THE
AMERICAN ASSOCIATION OF RETIRED PERSONS

SENATE LABOR AND HUMAN
RESOURCES COMMITTEE

HEALTH PRODUCT
TAMPERING

February 28, 1986

Good morning. I am Dr. Monroe Gilmour, a member of the Board of Directors of the American Association of Retired Persons and a retired physician. I appreciate the opportunity to be here and thank the Committee for holding hearings on this very timely issue of health product tampering. The American Association of Retired Persons (AARP) represents 22 million older Americans over the age of 50. This age group consumes a disproportionately large amount of drug products sold both by prescription and over-the-counter (OTC). Although they account for 11.7% of the population, older Americans consume 30% of the prescription drugs in this country. For OTC drug products, per capita expenditures by older householders are one-half to two-thirds higher than those of the average household.

AARP also operates the world's largest private mail-service pharmacy, filling seven million prescriptions a year for our members.

AARP would like to take this opportunity to commend the Food and Drug Administration for its quick and comprehensive actions surrounding the recent tampering incidents. As of last week, 1,300,000 Tylenol capsules had been inspected and top personnel mobilized to determine the parameters of the incidents and their effect on the consuming public. The FDA has followed up their investigations by holding meetings with consumer representatives and capsule manufacturers.

Johnson & Johnson is also to be commended for their quick actions to protect the public health. Their decision to ban capsule formulations for their OTC products was a bold yet reasonable response to repeated attacks on their products.

The question of whether all OTC capsule formulations ought to be banned seems to be hanging in the balance. AARP hopes that no such legislative or regulatory steps are taken to ban these products. It seems clear that market forces will and should be allowed to prevail. This is one clear case where the industry has huge incentives to do something, and those interests are totally consistent with the public health interest.

We feel that to ban capsules, or to do something "just to be doing something", would be a mistake. Of the forty-five or so OTC capsule products now on the market, some could easily be converted to caplets or tablets. But some, like the sustained-release products, could not readily be converted without compromising the effectiveness of the product.

To expend FDA's time, personnel and resources to promulgate regulations to deal with this problem seems rather futile in light of the nature of the incident -- really, of the crime ~~problem~~. The FDA regulations on tamper resistant packaging that resulted from the 1982 Chicago Tylenol tragedies were reasonable, comprehensive and successful in packaging OTC products in a variety of ways that would make casual tampering clearly evident. In this situation, we are no longer dealing with casual tampering -- current packaging has already addressed that problem. What we see are steps taken that are sophisticated enough to have foiled packaging safeguards. Such an intensity of effort falls more in the category of terrorism. Unfortunately, we do not see how any reasonable measures can succeed in thwarting a devious mind that is hell-bent on contaminating a product. For that matter, our food supply is also vulnerable to willfull contamination by any number of nefarious means.

When the 1982 tamper-resistant packaging regulations were being developed, AARP voiced strong concerns that packaging not prove to be "elder-proof", and that manufacturers would take into consideration minimum levels of accessibility in packaging their OTC products. We repeat those concerns on this sad occasion.

We feel that FDA resources, beyond what have already been expended, are better directed at continuing their present activities. Public education about Reyes syndrome, which is killing and causing severe brain damage in hundreds of children a year; work on completing the OTC drug product review to get unsafe and ineffective drugs off the market; and better enforcement capabilities are just a few examples which seem to be a more appropriate use of limited FDA funds. To invest more in finding regulatory solutions to a problem that there doesn't seem to be much we can do about would be unfortunate.

Certainly some effort is worth making, however. One thing that is clear is that consumers need to be aware to look for signs of tampering. The U.S. Pharmacopeia has produced a pamphlet, "Tips Against Tampering" that could be made more widespread. And Public Service Announcements helping people to be better detectors of possible tampering are certainly indicated. AARP, for its part, is looking into articles for our Newsbulletin and Modern Maturity magazine. Modern Maturity has the third largest circulation of any publication in the country, behind Readers Digest and TV

Guide. We hope that other groups, large and small, are also considering using their networks to educate people about tampering.

As an example of market forces at work, our AARP Pharmacy Service will have available an alternative dosage form of our own brand of acetaminophen (Tylenol®) that has been sold in hard-shell, pull-apart capsules with capsules made of soft gelatin that are sealed all around. We estimate that they will be available in May. We are also willing to disseminate written information about tampering at the point of sale with each OTC drug product. AARP already provides Medication Information Leaflets for Seniors (MILS) free of charge with over 90% of the prescription drugs we dispense.

We have noted other means of protecting a capsule more fully from tampering in addition to the soft gelatin. For example, capsules which have gelatin rings banded around the middle which prevents the two hard-shell parts from being pulled apart.

The response from our members to the recent tampering incidents has been minimal. We have received very few comments at our 11 walk-in pharmacies across the country and no letters that we are aware of at our National Headquarters. Informal interviews with our members using the AARP Pharmacy located at 1909 K Street, N.W. here in Washington have uncovered no alarm concerning capsules. Most people we spoke to viewed it as an isolated incident and said they would continue to use OTC capsules as they do with so many of their prescription medicines. T35 We feel that if there were widespread concern about the issue, we would be hearing about it.

In summary, the AARP commends the actions already taken to address the tampering incidents but hopes that further steps will not prove to be over-reactions to the problem.

Thank you.

The **Chairman**. Let's turn to you, Ms. Mathews.

Ms. **Mathews**. Good afternoon, Mr. Chairman and members of the committee. I am Odonna Mathews, vice president for Consumer Affairs at Giant Food, Inc., a regional supermarket chain with 137 supermarkets in Washington, DC, Virginia, and Maryland.

I will also shorten my statement and ask that the complete statement be included in the record.

As the consumer representative for a regional supermarket chain, I am in daily contact with consumers. Whenever there is a recall of a certain product, whether it is an over-the-counter drug or a food product, we receive an increase in the number of calls and letters to our consumer affairs office as well as an increase in the number of products returned to our stores.

This is the response we are currently experiencing in light of the incidents involving the Tylenol. Consumer awareness has definitely increased and consumers are more suspicious of anything unusual: a different color, odor or unusual package appearance.

Now that we have seen a recurrence of the Tylenol tragedies, I believe there is a general recognition that nothing is guaranteed to be 100 percent tamperproof even with the extra steps the Government and industry have taken to develop tamper-resistant packaging.

Consumers and the industry are vulnerable to individuals who are intent on tampering with products. Consumer concern with product tampering is significant. According to the 1985 Trends Survey published by the Food Marketing Institute, 50 percent of all shoppers were very concerned about tampering with over-the-counter drugs.

While this was a substantial decline from the 66-percent figure in 1983, consumers are uneasy about the possibility of product tampering and the current figure would probably be even higher if the survey were taken again today.

How much do consumers rely on themselves versus others to ensure product safety? According to the 1985 FMI Trends Survey, although many shoppers continue to rely on themselves to be sure that products are safe, this self-reliance has decreased from 48 percent to 38 percent.

This downward trend in consumer self-reliance is accompanied by an increased reliance on the Federal and State Governments to help keep products safe.

What do consumers expect from the manufacturing and retailing industries? They expect to buy products that are safe, but they realize that in cases of sophisticated tampering there is only so much that can be done to safeguard the public.

It is clear that Johnson & Johnson has placed consumer safety first and has taken all reasonable precautions to market a safe product. They are to be congratulated and serve as a role model for all companies on how to handle serious product-tampering situations.

Although Johnson & Johnson has decided to discontinue the sale of capsules, I believe it is premature for any government agency, Federal or State, to take any action to ban capsules all together. Until we know why and how some individual tampered with the

Tylenol capsules, it is senseless to take away a choice which some consumers prefer.

Consumers will show their preference for certain forms of the over-the-counter drugs they choose to buy in the weeks to come; however, initial reaction in Giant stores shows that the sales of caplets are up dramatically.

As a consumer advocate, I wonder if the pharmaceutical industry could develop new technologies that might better deter tampering. But it would seem that no matter how hard the industry works on developing these new technologies, tampering is still possible. Thus there may be limitations as to what can be done based on current technologies and costs.

It has been suggested that more effort be devoted toward informing consumers about precautions they can take to protect themselves from product tampering. I would like to see the industry, FDA and consumer representatives work together to develop appropriate safety messages.

However, until we know the specifics about the Tylenol tragedies, it is somewhat difficult to know what to educate consumers about.

It is important to emphasize that there is a good deal of important safety information on the product label already. We must remember that consumers can only absorb so much information at one time, especially when they are purchasing products when they are in a hurry and, in the case of over-the-counter drugs, may not feel well. Any consumer tips against tampering must recognize these facts and be realistic.

I would also ask the pharmaceutical manufacturers to work together through their trade associations to develop tamper-evident medicines and to share the information they learn about the best types of tamper-resistant packaging or products so that each company does not have to duplicate other similar efforts.

In conclusion, there are no easy solutions to the problem of product tampering. Consumers are frustrated because they cannot protect themselves.

The Government and industry have taken positive steps to protect them, but until the Government and industry discover what went wrong in the Tylenol cases it is difficult to tell consumers how to get more protection.

Consumer education may help, but it must be simple, to the point and realistic. Let us continue our efforts to look for more alternative solutions and to encourage cooperation among individual companies, the pharmaceutical industries, consumer representatives and the Government.

The CHAIRMAN. Thank you.

[The prepared statement of Ms. Mathews follows:]

TESTIMONY

SENATE LABOR AND HUMAN RESOURCES COMMITTEE

Odonna Mathews
Vice President, Consumer Affairs
Giant Food Inc.

February 28, 1986

Good morning, my name is Odonna Mathews, Vice President for Consumer Affairs at Giant Food Inc., a regional supermarket chain with 137 food-pharmacies in Washington, D.C., Virginia and Maryland. I am here to discuss some of the consumer issues related to tamper resistant packaging and the recent Tylenol tragedies.

As the consumer representative for a regional supermarket chain, I am in daily contact with consumers. Whenever there is a recall of a certain product, whether it is an o-t-c drug or a food product, we receive an increase in the number of calls and letters to our Consumer Affairs office as well as an increase in the number of products returned to our stores. That is the response we are currently experiencing in light of the incidents involving Tylenol. Consumer awareness has definitely increased and consumers are more suspicious of anything unusual--a different color, odor, or unusual package appearance.

Now that we've seen a recurrence of Tylenol tamperings, I believe there is a general recognition that nothing is guaranteed to be 100% tamper-proof, even with the extra steps the government and industry have taken to develop tamper-resistant packaging. Consumers, and the industry, are vulnerable to individuals who are intent on tampering with products.

Consumer concern with product tampering is significant. According to the 1984 Trends Survey, published by the Food Marketing Institute, 50% of all shoppers were very concerned about tampering with o-t-c drugs. While this was a substantial decline from the 66% figure in 1983, consumers were uneasy about the possibility of product tampering. And the current figure would probably be even higher if the survey were taken again today.

The 1983 FMI Trends Survey showed that exactly half of the shopping public (50%) checked some specific product for signs of tampering. About half (49%) stopped buying products that they believed could easily be tampered with. Some consumers had talked to store employees or store managers about incidents of product tampering (12%) or returned products that they suspected had been tampered with (6%).

How much do consumers rely on themselves vs. others to ensure product safety? According to the 1985 FMI Trends Survey, although many shoppers continue to rely on themselves to be sure that products are safe, this self-reliance has decreased from 48% to 38%. This downward trend in consumer self-reliance is accompanied by an increased reliance on the federal and state government to keep products safe (from 22% to 31% and 3% to 6%, respectively).

What can consumers expect from the manufacturing and retailing industries? They expect to buy products that are safe, but they realize that in cases of sophisticated tampering, there is only so much that can be done to safeguard the public. It is clear that Johnson and Johnson has placed consumer safety first and has taken all reasonable precautions to market a safe product. They are to be congratulated and serve as a role model for all companies on how to handle serious product tampering situations. They have kept consumers, the government, and the media informed of what has been found and were not reluctant to withdraw their product from the market even if it meant sacrificing sales. They have clearly taken steps in the consumers' best interest.

Although Johnson and Johnson has decided to discontinue the sale of capsules, I believe it is premature for any government agency (federal or state) to take any action to ban capsules altogether. Until we know why and how some individual tampered with the Tylenol capsules, it is senseless to take away a choice which some consumers prefer. Consumers will show their preference for certain forms of o-t-c drugs they choose to buy in the weeks to come. However, initial reaction in Giant stores shows that the sales of caplets are up dramatically.

As a consumer advocate, I wonder if the pharmaceutical industry could develop new technologies that might better deter tampering. But it would seem that no matter how hard the industry works on developing these new technologies, tampering is still possible. Thus, there may be limitations as to what can be done based on current technologies and costs.

It has been suggested that more effort be devoted toward informing consumers about precautions they can take to protect themselves from product tampering. I would like to see the industry, FDA and consumer representatives work together to develop appropriate safety messages. However, until we know the specifics about the Tylenol tragedies, it is difficult to know what to educate consumers about.

At Giant, we have implemented several consumer safety information programs. Our "Read the Label" program encourages consumers to read o-t-c drug labels for important warnings on their proper use and when to take or avoid certain medications based on certain medical conditions, allergies, or drug interactions. Symbols on Giant o-t-c drug labels tell at a glance when certain drugs should be avoided by those with certain health problems such as high blood pressure or diabetes. The program reminds consumers not to accept any o-t-c drug if the seal is broken or missing, and to let the pharmacist or store manager know if this occurs.

My point in explaining this program is to emphasize that there is a good deal of important safety information on the product label already. We must remember that consumers can only absorb so much information at one time, especially when they are purchasing products when they are in a hurry and in the case of o-t-c drugs, may not feel well. Any consumer tips against tampering must recognize these facts and be realistic.

What have we learned from all of this? Clearly, we've learned how a company should respond in cases of serious product tampering. Give full disclosure about exactly what happened. Be accessible to the media. Give customers a full refund or replacement and a toll-free number to call for further information. By doing those things, Johnson and Johnson has enhanced its credibility and increased public confidence by showing that the safety of its customers is its number one priority. I would hope that all companies could respond in such an open and informed manner.

I would also ask the pharmaceutical manufacturers to work together through their trade association to develop tamper evident medicines, and to share the information they learn about the best types of tamper resistant packaging or products, so that each company doesn't have to duplicate other similar efforts.

In conclusion, there are no easy solutions to the problem of product tampering. Consumers are frustrated because they can't protect themselves. The government and industry have taken positive steps to protect them. But until the government and industry discover what went wrong in the Tylenol cases, it is difficult to tell consumers how to get more protection. Consumer education may help, but it must be simple, to the point and realistic. Let us continue our efforts to look for more alternative solutions and to encourage cooperation among individual companies, the pharmaceutical industries, consumer representatives and the government.

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The CHAIRMAN. I want to thank all three of you for the statements that you have given. I think it is very important that we have the point of the view of the consumers in this country.

Ms. Steorts, let me ask you this, and each of you others, as well. How do the the consumers in this country view the performance of the Food and Drug Administration in this current crisis?

Ms. STEORTS. I think they see their performance positively. I think that it was very quick action, both on the part of the FDA as well as on the part of the industry; and I think that this is the kind of quick reaction that is important.

We cannot drag our feet on this kind of thing. I think we need fast solutions.

The CHAIRMAN. Thank you. Dr. Gilmour, do you feel the same?

Dr. GILMOUR. Judith Brown, who is our health analyst at AARP specializing in pharmaceuticals, and who has been in touch with AARP's membership during this crisis, will respond to that.

The CHAIRMAN. We are very happy to have you here, as well.

Ms. BROWN. Thank you very much.

We believe that the Food and Drug Administration is one of the most popular agencies. As a matter of fact, I just read a survey to that effect yesterday. I believe it was a national survey. We at AARP have very few complaints.

Our complaints would be only along the lines of decreased funding for the FDA, but we think they are doing a great job, especially in this situation.

The CHAIRMAN. We think they do a tremendous job also. We can always point to some things that we disagree with, but in all honesty it is a remarkable organization, the best in the world.

How about you, Ms. Mathews? Do you feel the same?

Ms. MATHEWS. I would add that based on FDA's past history, and their accessibility to the media which has reached most individuals, I believe, that we have taken steps to prevent it.

I think that consumers are frustrated because we have not found the culprit in this case; but I think there is strong recognition that FDA has taken responsible action, quick action, and will continue to monitor it and see what else could be recommended in the future.

The CHAIRMAN. Do consumers feel that the FDA, after the 1982 Tylenol deaths, did everything that they should have done or that they took reasonable steps within their power to minimize the chances of reoccurrence of these types of incidents? Basically, do you all feel that they did the best they could have done?

[Witnesses nodded in the affirmative.]

The CHAIRMAN. All three of you do.

Ms. MATHEWS. It is difficult to imagine, really, what else could be done, other than to, through some miracle perhaps, find out what went wrong.

The CHAIRMAN. I look to the industry, also, because just this year the members of this committee worked out the agreement and the voluntary regulations between the FDA and the aspirin manufacturing community with regard to Reyes syndrome.

The FDA really jumped on that, and did a very good job. They were not necessarily sure that we had to have regulations, but when the industry agreed that that is what we should do to resolve the problem because some of the aspirin manufacturers were not complying with letting people know about Reyes syndrome, we were able to get them both together and, I think, do what was in the best interests of the consuming public.

What specific steps can you folks give us as to what the drug industry should take or can take to ensure consumers a higher level of protection from drug tampering? Or do you feel that they have all been mentioned here today by the experts?

We will start with you, Ms. Steorts.

Ms. STEORTS. Well, I think it is tough right now to know what is the next step. I think, frankly, that we really have to look at consumer responsibility.

I think the consumer is going to have to change his or her ways of doing business. I think they need to be much more cautious in their purchasing habits and I also think the retailer has a responsibility here, too, particularly the pharmacist, to check those shelves and to really be sure that, indeed, products have not been tampered with.

The CHAIRMAN. Dr. Gilmour or Ms. Brown?

Ms. BROWN. We don't really see what other kinds of manufacturing safeguards can be taken that just will not be totally prohibitive, cost-wise; and, even then, there is no assurance that it is going to be tamperproof.

So we are satisfied with the regulations that resulted from the 1982 tragedies.

The CHAIRMAN. All right. Dr. Gilmour?

Dr. GILMOUR. We do think, however, that research and investigation should be continued by industry.

The CHAIRMAN. I think one thing that this hearing has done is demonstrate that there is a large effort in research to find ways of resolving these difficulties.

Ms. BROWN. As Dr. Gilmour said in his testimony, the market forces are clearly in accordance with public health interests to make capsules so that they are not able to pull apart. That is clearly indicated.

The CHAIRMAN. Let me ask just one final question before I turn to Senator Kennedy.

Is any Federal legislation or regulation initiative necessary at this time, in your opinions? We will start with you, Ms. Mathews, then we will go to Ms. Steorts.

Ms. MATHEWS. I do not think further regulation, beyond the tamper-resistant packaging requirements that have already been established, appears to make much difference at this point. I think that has been the consensus of the experts who have testified earlier.

The CHAIRMAN. On that point, since you deal so much with consumers in your industry, in your opinion, do consumers have a high degree of confidence in capsules?

Ms. MATHEWS. Well, I would say what has happened makes people question, and say "It could happen to me. It could happen with almost any type of consumer product."

I think that some people prefer the capsules. Therefore, to have that choice taken away through a regulation would be a detriment to those consumers.

The point is, that as industry develops new types of dosage forms, whatever they may be, through the new technologies, that consumers will have a choice. If some are better than others, yes, I would like to know that as a consumer.

But I think the tamper-resistant technologies that are out there do a lot toward achieving that effort.

The CHAIRMAN. Thank you. Ms. Steorts.

Ms. STEORTS. Mr. Chairman, I feel that no new regulations are necessarily needed at this point, but I do feel as we look at our overall health issues and the major concerns that consumers have about them, it is now time for the Government to review what the health and safety agencies are doing because there is a tremendous amount of overlap.

I think it might behoove this committee to start a review of the various agencies and evaluate what each agency is doing.

For example, the Consumer Products Safety Commission has regulatory authority over the child-resistant closure and the FDA has authority over everything else. I think that possibly some of those functions could be combined, which would be much more effective for both the consumer as well as the industry.

The CHAIRMAN. That is a good suggestion.

Ms. Brown.

Ms. BROWN. We, at AARP, would really hate to see more time and energy spent in promulgating regulations or legislative actions beyond what has already been done to address what is essentially a terrorist act.

The CHAIRMAN. Thank you. I will turn to Senator Kennedy at this point.

Senator KENNEDY. Thank you very much.

Dr. Gilmour, you have a large mail order business, do you not, pharmacy business?

Dr. GILMOUR. Yes. Seven million prescriptions a year.

Senator KENNEDY. After the 1982 tragedies, did that affect your business?

Dr. GILMOUR. Well, the business was then already growing; I think it continued to grow.

Do you have any statistics on that, Judi?

Ms. BROWN. No.

Dr. GILMOUR. It has continued to grow. We have just opened another pharmacy in Richmond.

Senator KENNEDY. Did you make some changes at that time, after the 1982 tragedies, in terms of your mail order business?

Dr. GILMOUR. Not to my knowledge, but I was not associated with it then.

Ms. BROWN. Besides pulling Tylenol off the shelves, no; and the same thing in this instance, except as Dr. Gilmour said, we will be providing an alternative form of soft-sealed gels for of our own AARP brand of acetaminophen.

Senator KENNEDY. I would be interested in your reaction with regard to elderly people, senior citizens and others. One of the dilemmas that we find ourselves in is that if we alter and change these various procedures in a number of additional ways to provide additional safety that this may present some additional kind of impediment to senior citizens in being able to use products.

Is this a matter of concern?

Dr. Gilmour. Do you mean to their accessibility to the products?

Senator Kennedy. Yes.

Dr. Gilmour. Well, it is a matter of some concern; but it is already so difficult for many of them to use some products that we feel that the advantages of making them much more difficult would not be useful.

Senator Kennedy. I suppose what I am driving at is whether there are ways and means to provide additional information to make the products more tamper-evident rather than tamper-resistant so that the seniors would be able to get additional kinds of protection.

I think there is a distinction there and I would be interested in your comments.

Ms. Brown. As to providing additional information, we certainly agree. We have already secured articles for Modern Maturity, the AARP News Bulletin and some of our other printed materials. We are also willing to disseminate information on tampering with the 7 million prescriptions we fill every year as well as with the over-the-counter products.

Since 1982, we have been providing PPI's, or medication information leaflets for Seniors [MILS], with most of our prescriptions, so the concept of having written information accompanying every product is not new to us.

The Chairman. Ms. Steorts, can you tell us what role the Consumer Product Safety Commission played in the development of the regulations after the 1982 tragedies?

Ms. Steorts. Yes, Senator Kennedy.

We tried to work very closely with the Food and Drug Administration at that particular time; but what happened after the development of the tamper-resistant packaging—and this is why I think that these health related issues need to be combined in one agency—is that after Johnson & Johnson got everything all put together with their tamper-resistant packaging, the CPSE then found when we investigated the marketplace for compliance on child-resistant closure that the 24-tablet Tylenol package was failing our child-resistant closure regulation by one-thousandth of an inch, which meant it was a failure.

I think that this is, indeed, an unfortunate situation. Johnson & Johnson was unbelievably cooperative in correcting that problem; but I don't think they needed to go through that, nor do I think that the consumers needed to go through that kind of a situation.

So I feel that where you have health-related issues, they really should be together in one agency. I am sure that the CPSC now will work very closely with the FDA on developing any new programs, but I think it is essential that there be close cooperation to avoid problems such as took place in the past.

Senator Kennedy. Ms. Mathews, one of the related issues to the ones that we are considering here today is the safety problems in the protection of the consumer in the range of other ingested substances. We can all imagine what they are.

I would be interested to hear from you, and maybe the other members of the panel, whether we as a society, governmental agencies or the private sector are really doing enough in this area to try to give the kinds of assurance to the public and consumers that they ought to receive.

Ms. MATHEWS. As I indicated in my testimony, consumers have shown a decrease in their reliance on the steps they can take to protect themselves and are looking toward our Government to protect them as well as the industry.

My feeling is, in talking with customers who have returned products, who have suspicions about perhaps something unusual, that they are questioning more products and I think that that is healthy because we cannot just take things for granted as, perhaps, we have in the past.

I don't want us, however, to get into a situation of overalarm because, by and large, our food and drug supply is a very safe one; but I think if consumer education messages could be developed and distributed, that that would be a healthy and positive thing to do.

By having the hearings today, you are making every effort to determine if, in fact, something more could be done.

Senator KENNEDY. Ms. Steorts.

Ms. STEORTS. I agree with Ms. Mathews.

Senator KENNEDY. Well, I think that is very important and reassuring.

I want to thank the witnesses very much; and, again, to thank you, Mr. Chairman. I think this hearing has been very positive and very constructive.

I look forward to the report of the FDA and look forward to working with you in a continuing oversight function on this particular issue, which has brought a tragedy to several individuals and their families, and also do whatever we can to insure the kind of consumer safety that we possibly can.

I thank the Chair for holding these hearings.

The CHAIRMAN. Thank you so much, Senator.

We appreciate all of you coming. I think you have added a great deal to the hearing and we appreciate the effort you have put forth.

Our final panel will be Mr. James C. Cope, president of the Proprietary Association accompanied by Daniel F. O'Keefe, Jr., vice president and general counsel and R. William Soller, Ph.D., who is vice president of scientific affairs with the Proprietary; and then Peter Fink, president and chief executive officer of R.P. Scherer Corp.

We are very happy to welcome you to this committee. We look forward to listening to your testimony.

We will turn to you, first, Mr. Cope.

I might mention both Senator Kennedy and I have appointments that are long since due. So if you can summarize your statements, I think that will really help us.

We are going to put your full statements into the record.

STATEMENTS OF JAMES D. COPE, PRESIDENT, THE PROPRIETARY ASSOCIATION, ACCOMPANIED BY DANIEL F. O'KEEFE, JR., SENIOR VICE PRESIDENT AND GENERAL COUNSEL AND SECRETARY, AND R. WILLIAM SOLLER, PH.D., VICE PRESIDENT, SCIENTIFIC AFFAIRS; AND PETER R. FINK, PRESIDENT AND CHIEF EXECUTIVE OFFICER, R.P. SCHERER CORP., ACCOMPANIED BY DR. DESMOND DAVIS, VICE PRESIDENT AND CHIEF SCIENTIFIC OFFICER

Mr. COPE. Thank you, Mr. Chairman.

I have a condensed statement of eight pages and I will summarize that even further in the next few minutes.

The CHAIRMAN. Thank you.

Mr. COPE. I am Jim Cope, president of the Proprietary Association. On my right is Mr. Dan O'Keefe and on his right Dr. Bill Soller.

We represent, as you know, the manufacturers of over-the-counter medicines, products which consumers use almost every day in self-care. Self-care, as you must know, is the predominant form of health care in this country.

We, like everyone, are deeply concerned about the events in Westchester County and the fact that one of our members' products—a prominent member and prominent product—was contaminated and used to kill an innocent human being.

The recent tampering brings back, as I am sure Dr. Hayes will agree, dark memories of 1982. I would just like to recount where we went from there and where we are right now, because there have been questions along those lines already today.

As you know, immediately after the Chicago story broke in 1982 we pledged to do three things: First, to put our products in tamper-resistant packaging, TRP, just as quickly as industrial capacity would permit; second, we would do that with or without legislative or regulatory requirements; and third, we would work with the Food and Drug Administration get into place a national uniform regulation requiring mandatory standards for tamper-resistant packaging. We met those commitments, and the results are rewarding.

Our medicines today, Mr. Chairman, are the most safely packaged consumer goods in the world.

There are two basic concepts in the TRP regulations, and we all know what they are. First—and this has already been said here today—tamperproof packaging is impossible. The second basic concept is simply not to try to keep people from getting into the packages, which has been a problem, but to try to keep them from opening them without leaving evidence, some kind of evidence of tampering.

Today, as Senator Kennedy, I think, read, there are 11 forms of TRP in use, and every over-the-counter medicine that is taken in the body must have at least one form of that packaging.

Now, I can report to you that the concept of establishing a regulation was simple, but getting it in place was very difficult. And once we had it in place, we immediately learned three lessons. First, making packages harder to open without leaving evidence sometimes meant making them harder to open, period. The manually and physically impaired, including some elderly, especially complained, and we think rightly. So, we had to reexamine that, as you have heard from the CPSC and the FDA today, and we hope and think that those concerns have been accommodated.

The second lesson we learned was that a TRP seal—for example, a clear plastic shrink wrap—was not much protection if the consumer did not know what to look for. So, we had to add new words to labels describing what the TRP feature should look like; and we also had to imprint a distinctive feature over the TRP seal.

The third lesson we learned was that TRP is, happily, an evolving science. The technology is a continuum.

Since 1982, technology has advanced and TRP has become more sophisticated and more effective. We count 18 advances in packaging since TRP was first required in 1982—and there probably will be more. These include the use of tearstrips to insure protection but permit easier access for the manually impaired, including some elderly; use of neck seals with unique imprinted designs to discourage counterfeiting; and better glue to increase the probability of tearing the outer cardboard when the flaps are opened. We have listed these advances, and will submit the list for the record.

[Information supplied follows:]

The Proprietary Association

Post 1982 Examples of TRP Advances

Industry's Commitment to High Quality Tamper-Resistant Packaging

Since the introduction of the first wave of tamper-resistant packaing, industry's commitment to high quality tamper-resistant packaging has been sustained. Examples are provided below of advances in TRP since the initial 1982 wave.

1. Evolution of TRP to permit tamper-evidency with accessibility for the elderly and disabled. For example:
    a. introduction of a "rip-here" tab on the neck seal to enhance accessibility;
    b. replacement of certain "low accessibility" ring sealed metal caps with high quality plastic neck seals with enhanced accessibility;
    c. introduction of more fragile break-away caps; and
    d. introduction of tear strips to make TRP removal easier.
2. Improvement in adhesive materials for blister (strip) packs.
3. Replacement of neck seal with more tamper-evident material.
    a. e.g., plastic neck band replaced with ring sealed metal cap.
4. Sonic-sealed capsules.
5. Locking capsule with a reduced gripping surface on one end to make the capsule inherently more difficult to open.
6. Banded capsules.
7. Thinner/more ripable paper for cardboard boxes.
8. Use of a more free-flowing glue to cover the entire end flap area of outer boxes in order to make entry more tamper evident.
9. Change from glued end flaps of outer boxes to the tamper-evident tape across the flaps.
10. Second generation sealing tape of greater fragility.
11. Taping of side seams with tamper-evident tape.
12. Use of induction sealed blind-end plastic tubes.
13. Enlargement of neck bead of bottle to a size equal to or larger than the base of the cap to give a larger obstacle over which to put the neck band and therefore a stronger bonding of the neck seal.

(Over, please)

14. Use of shrink-wrap of the entire bottle.

15. Use of metal cans for the outer container, which were subsequently replaced with a shrink-wrap of the box.

16. Improvements of the inner seal material to enhance fragility.

17. Important improvements in reliability of TRP in manufacture through new applications in statistical quality control, including, for example, use of computers to rapidly assess patency of seals during manufacture thus minimizing the potential for factory release of defective TRP.

18. Use of unique logos printed on TRPs.

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Mr. COPE. Since 1982, we have done one other important thing that has been alluded to today, and that is perhaps the most important one of all. We have joined with Government and with others in a continuing effort to raise public awareness of their own responsibilities for self-protection.

Our brochure, adapted from the USDA's "Tips Against Tampering," is a keystone in this effort and more than 1 million copies of this have been distributed through such programs as the National Poison Prevention Week.

But with all we have done, and without warning, we have another death. So what are we doing about that?

On February 18, last week and 2 working days after the second contaminated bottle of Tylenol was discovered, we reconvened the expert technical committee which served the country, the Congress, and the FDA so well in 1982. It consists of many of the same experts that served in 1982, and importantly, has FDA representation and participation.

Also, 3 days ago, we convened a technology study subgroup of that expert technical committee. Their job is to survey all new packaging technologies and dosage forms. They will search for ways to build upon and to improve the current tamper-resistant seals already used on billions of OTC packages.

I can report that the expert technical committee has reached four conclusions:

First, tamperproof packaging is still impossible.

Second, the tamper-resistant packaging developed in 1982 is still sound, and its success, as we heard mentioned earlier, is demonstrated by a sharp decline in tamperings reported to FDA since it was instituted.

The third recommendation is that industry should redouble its efforts to develop even better technologies.

Fourth and last, each and every company in this industry was asked to review its own security systems, covering all aspects of the production and use of tamper-resistant seals and seal materials.

Our executive committee and board of directors met and adopted these conclusions and recommendations and, Mr. Chairman, as you know, each individual company in this industry is evaluating these matters at this moment.

One of the questions on our plate is this: Like J & J, should industry voluntarily abandon the use of capsules? Wouldn't that be the quick and easy answer? Obviously, we respect the decision made by one of our largest members, J & J. That was a responsible decision for that company to make under the circumstances—after all, their capsule product was being used to kill people.

If the rest of the industry could end tampering by doing away with capsules, we would; but we cannot do it because we know that would not stop tampering.

It might even be possible that the elimination of capsules or any particular drug delivery system would accomplish very little, except to refocus tampering activity to some other dosage form or some other type of consumer commodity. If the removal of capsules from the market were to drive the criminal to tamper with another form of OTC medicine or with other consumer commodities, we would not have accomplished anything.

In fact, "copycat" tampering might even be then more of a public concern than it is now. Also, Mr. Chairman, as has been said earlier, capsules have had more than 100 years of safe use, and we produce about 10.5 billion of them a year in the OTC medicines industry. They are the preferred way to take OTC medicines for many people, and there are six reasons for that:

First, they are easier to swallow for many, many people. Consumers report that with capsules there is less aftertaste or gagging.

The second attribute, through printing and color combinations, capsules help consumers and health professionals know which medicines are which. This product distinction is also important in cases of drug overdose.

The third advantage is that capsules provide a proven, standardized, and often preferred means of delivering time-release medications. This enhances patient convenience and compliance.

Fourth, they are less susceptible to damage during shipping.

Fifth, capsules are necessary for some medicines which cannot easily be put into tablet form.

And finally, just as in 1982, a recent consumer survey shows that a majority of consumers still prefer capsules.

Nevertheless—and I think this is important to repeat—if doing away with capsules would end the risk of tampering, we would be willing to do so. But we know that would not work.

Capsules are no more or less vulnerable to criminal tampering than many other products that Americans buy and use, including our OTC medicines.

The Chicago and New York cases, first and last, are criminal acts. Our best chance is to catch the criminals and bring them to justice. Congress of course recognized this when it passed Senator Thurmond's Federal Anti-Tampering Act of 1983, which you know we were instrumental in urging you to do.

Let me assure you that in the public's interest as well as our own we will continue to redouble our efforts to further improve our packaging and our technology and manufacturing, and to make our products—which are already the best-packaged consumer goods—even more tamper-resistant.

We feel it important, however, as I think Dr. Hayes said, not to allow the terrorists or the criminals to take over. We think that would be a mistake. We think we should maintain the agenda and continue on with business and life essentially the way we have.

In closing, let me say that for us the best hope we have to control criminal tampering has five facets:

First, an industry which packages its products in the most effective and yet reasonable tamper-resistant packaging; second, a dedicated—and it is—and importantly, an adequately funded and staffed Food and Drug Administration; third, effective law enforcement; fourth, appropriate vigilance on the part of all in the distribution chain—manufacturer, wholesaler, and retailer; and fifth and last, and probably the most important, an informed and circumspect public which must, and I am sure is, exercising care in buying and using all consumer commodities that they ingest, including those they use in self-care.

The CHAIRMAN. Thank you, Mr. Cope.

[The prepared statements of Mr. Cope and the Proprietary Association and responses to questions submitted by Senator Kennedy follow:]

STATEMENT
OF
JAMES D. COPE, PRESIDENT
THE PROPRIETARY ASSOCIATION
ON
SECURING THE CONTENTS OF OTC MEDICINE PACKAGES
BEFORE THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
FEBRUARY 28, 1986
WASHINGTON, D.C.

Good morning, Mr. Chairman and members of the Committee, I am James D. Cope, president of The Proprietary Association. With me this morning are Daniel F. O'Keefe, Jr., our senior vice president, general counsel and secretary, and R. William Soller, Ph.D., our vice president-scientific affairs.

The Proprietary Association represents manufacturers and distributors of nonprescription, over-the-counter ("OTC") medicines such as pain relievers, cold medicines, antacids and many others. OTC medicines are an essential part of our self-care system. Americans use OTCs to take care of fully a third of their everyday aches and ailments; they call or visit the doctor for only one in ten of these problems. PA members account for about 95 percent of the sales of OTC medicines.

Our industry is deeply concerned — stunned and saddened — with the recent tragedy involving the malicious, criminal tampering with two packages of Tylenol capsules. We are distressed that one of our products — products relied upon by millions to relieve pain and discomfort — has been adulterated by criminal act and used to inflict death upon an innocent human being.

The recent tampering case in Westchester County, New York, raised for all of us dark memories of the Chicago tragedy in which seven persons died in 1982.

Within days after the Chicago story broke, The Proprietary Association and the OTC industry committed to the public, to Congress, to FDA, to the states and to ourselves that we would do three things:

1. We would place products in tamper-resistant packaging (TRP) as quickly as industrial capacity permitted;
2. We would do so with or without legislative or regulatory requirements; and
3. We would cooperate with government to establish national and mandatory standards of tamper-resistant packaging.

The conversion to TRP cost the OTC industry between $500 million and $1 billion. The costs continue — with slower production lines, high technology sealing materials and expensive machinery to apply the materials to packaging. But the results are rewarding. Our OTC medicines today are the most safely packaged consumer goods in the world.

The basic concept of the tamper-resistant packaging regulation put in place in 1982-83 was twofold:

1. Tamper-proof packaging is impossible. FDA went further than we did on this point. They said that any labeling suggesting that a package

is "tamper-proof" would be considered false and misleading and a violation of federal law.

2. The second basic concept then was not to try to keep people from opening OTC packages — i.e., tamper-proof — but to keep them from opening them without leaving evidence — a punctured foil seal, for example.

Today there are 11 forms of TRP in use. They range from simple aerosol containers which are obviously tamper-resistant to clear plastic shrink seals around an entire product — a system that is not at all obvious without a notice of its presence and purpose printed on the medicine container directly. Today, every OTC that is taken into the body must have at least one form of TRP protection; many use several.

The concept was easy; putting it in practice was hard. It took time and old-fashioned trial and error methods. Almost as soon as the new packaging began rolling off production lines, we learned three costly lessons:

1. Making packages harder to open without leaving evidence sometimes meant making them harder to open — period. The manually and physically impaired, including the elderly, especially complained. And rightly so!

2. A TRP seal — for example, a clear plastic shrink wrap — wasn't much protection if the consumer didn't know to look for it. We had

to add new words to labels describing what the TRP should look like. We also had to imprint a distinctive feature over our TRP.

3. Finally -- and importantly — we learned that TRP was an evolving science.

In the time since 1982, technology has advanced and TRP has become more sophisticated -- more effective. We count at least 15 advances in packaging since TRP was first required. These include the use of tearstrips to insure protection but permit easier access by the manually ~~physically~~ impaired, including some elderly; use of neck seals with unique, imprinted designs to discourage counterfeiting; and better glue to assure tearing of outer cardboard flaps when opened.

Since 1982 we have done one other important thing — perhaps the most important thing of all. We have joined with government and with others in a continuing effort to raise public awareness of their own responsibilities for self-protection. Our brochure, Tips Against Tampering, is a keystone to this effort and more than one million have been distributed through such programs as Poison Prevention Week.

As sad as it may be, Mr. Chairman, the truth is that an alert public — an informed and knowing people — is the best protection we will ever find against the criminal who would use our own medicines against us.

But for all we've done — and are doing — and without warning — we have another case of tampering and another death. What are we doing about it?

On February 18, two working days after the second contaminated bottle of Extra-Strength Tylenol capsules was reported, the PA's Expert Technical Committee was reestablished and met. It consisted of many of the same experts that comprised the group that advised both industry and FDA in 1982. As in 1982, representatives of FDA sat with the committee, provided information and listened to its deliberations. A technology study subgroup met on Tuesday of this week to begin an intensive survey of all possible new packaging technologies and dose forms. They will be exhaustive in their search for ways to build upon — to improve the tamper-resistant seals already used by billions of OTC packages today. The Expert Technical Committee reached four conclusions:

1. "Tamper-proof" packaging is still impossible;

2. The tamper-resistant packaging system developed in 1982 is still sound: Its success is demonstrated by a sharp decline in tamperings reported to FDA since it was instituted;

3. Industry should redouble its efforts to develop even better technologies to serve the TRP system now in place; and

4. All OTC manufacturers should review their security systems covering all aspects of the production and use of tamper-resistant seals and seal materials.

The PA leadership endorsed all of these conclusions and recommendations without dissent. Individual companies already are acting on the suggestions.

But now the inevitable question arises: Wouldn't the quick and easy answer be to ban or restrict capsules for all OTC uses?

PA respects the decision of Johnson & Johnson to drop capsules from its OTC product line. This was a responsible decision for that company to make under the circumstances. Their capsule product was being used to kill people!

If the rest of the OTC industry could end the tampering by doing away with all capsules it would do so. But we know it can't do that. In fact, it is possible that the elimination of any particular drug delivery system would accomplish very little except to refocus tampering activity to other areas.

If the removal of capsules from the market drives the criminal to tamper with other consumer commodities or another form of OTC medicines, no good will have been accomplished. And, in fact, "copy cat" tampering might then be even more of a public health concern than is now the case with capsules.

Moreover, capsules are a valuable and sometimes preferred way to take OTC medicines with more than a hundred years of safe use. Medicines packaged in capsule form are important for at least six reasons:

1. They are easier to swallow. Consumers report that with capsules there is less aftertaste or gagging.

2. Through printing and color combinations, capsules help consumers and health professionals know which medicine is which. Product

distinction is also important in the correct handling of overdose cases.

3. Capsules provide a proven, standardized and sometimes preferred means to deliver timed-release medications. This enhances patient convenience and thus compliance.

4. Capsules are less susceptible to damage during shipping.

5. Capsules are necessary for some medicines which cannot easily be put in tablet forms.

6. And finally, just as in 1982, a survey taken after the New York case suggests that a majority of consumers still prefer capsules.

Nevertheless — and important enough to repeat — if doing away with capsules for OTC medicines would end the risk of tampering, industry would be willing to do so. But it would not work. Capsules are no more or less vulnerable to criminal tampering than many other products that Americans buy and use, including OTC medicines in other dose forms.

The New York case, like the Chicago case before it, was first and last a criminal act. Our best chance — in this or any other such case — is to catch those who did it and bring them to justice. Congress itself recognized this by enacting ~~the~~ Sen. Th Federal Anti-Tampering Act in 1983 to make it a federal, criminal offense to tamper with consumer products.

Let me assure you that — in the public's interest as well as our own — we will continue to redouble our efforts to develop improved technology in manufacturing and packaging and to make our products — already the best-packaged consumer goods in the world — even more tamper-resistant. We feel it important, however, not to allow isolated acts of murder or madness to dictate how a nation self-medicates and carries on its business and life. That's putting the criminals in charge and would, in our judgment, be extremely unwise.

In closing, let me say that for us the best hope we have to control criminal tampering has five facets:

1. An industry which packages its products in the most effective and reasonable tamper-resistant form technology can provide;

2. A dedicated and — importantly — adequately funded and staffed Food and Drug Administration;

3. Effective law enforcement;

4. Appropriate vigilance on the part of all in the distribution chain: manufacturers, wholesalers and retailers; and

5. An informed and circumspect public which exercises care in buying and using consumer commodities, including over-the-counter medicines they use in self-care.

Thank you.

JDC/JTW/JHL/DOK/MS/smd
2/27/86

THE PROPRIETARY ASSOCIATION

[illegible] N.W. Washington, D.C. [illegible]
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STATEMENT
OF
THE PROPRIETARY ASSOCIATION
ON
SECURING THE CONTENTS OF OTC MEDICINE PACKAGES
BEFORE THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
UNITED STATES SENATE
FEBRUARY 28, 1986
WASHINGTON, D.C.

I. INTRODUCTION AND SUMMARY

I am James D. Cope, President of The Proprietary Association. With me this morning are Daniel F. O'Keefe, Jr., our Senior Vice President, General Counsel and Secretary, and R. William Soller, Ph.D., our Vice President - Scientific Affairs. I would like to summarize the main points of my written statement, but ask that it (and the appendices to it) be included in their entirety in the official hearing record.

The Proprietary Association, which we call the "PA", is the century-old trade association representing manufacturers and distributors of nonprescription, over-the-counter ("OTC") medicines such as pain relievers, cold medicines, cough syrup, and many others, some of which you probably have in your medicine cabinet at home. Some of these products are among the most commonly used and widely known consumer products in the United States. Currently PA members account for about 95 percent of the sales of such products.

Our industry is deeply concerned -- stunned and saddened -- about the recent tragedy involving the malicious, criminal tampering with two packages of Tylenol capsules. We are distressed that one of our products -- products which are relied upon by millions to relieve pain and discomfort -- has been poisoned by criminal act and used to inflict death upon a trusting consumer.

OTC medicines are the most safely packaged consumer commodities in the world. But there is no tamper-proof or criminal-proof packaging or product form that will deter the dedicated, criminal or insane tamperer.

Industry will do its part to try to improve tamper-resistant packaging. It is now engaged in an aggressive effort to find new technologies to improve further the tamper-resistance of OTC medicines and packaging. But as a nation, we must not act reflexively to ban or restrict products or dosage forms where we may only embolden the dedicated criminal or insane tamperer to try again with other products, including OTC medicines. We must not permit isolated acts of murder to force society to change its system of self-medication or eliminate important dosage forms, with no assurance of improved public safety, which is our common goal.

II. THE PROBLEM IN PERSPECTIVE

It may be helpful to the Committee if we review a few points in order to put this problem in its proper perspective.

A. The Role of Self-Medication in the Nation's Health Care System

OTC medicines are an integral part of the health care system in the United States. These products are composed of ingredients whose pharmacological actions are well understood, and there is a wide margin of safety in their use. Their safety, effectiveness, quality control, and manufacturing processes are extensively regulated by the U.S. Food and Drug Administration. OTC medicines provide safe and effective treatment for a multitude of ailments. Self-medication is the predominant form of health care in this country: About one-third of everyday ailments are treated with OTC medicines, which account for only two cents of the nation's health care dollar. OTC medicines are inexpensive and conveniently available in many thousands of retail outlets -- including pharmacies, food stores, and discount and department stores -- everywhere. Relief from a headache, for example, can be obtained for about a nickel. Self-medication today constitutes an early and fundamental level of health care; without self-medication, physicians would be overwhelmed by patients seeking relief for symptoms and ailments that are often self-treatable. Thus, use of OTC medicines provides an economical and convenient alternative to more costly and time-consuming physician visits.

The U.S. Department of Commerce has underscored the significance of OTC medicines in the nation's health care system. A statement, made in 1978 by the Commerce Department, has even more validity today.

> Self-medication with proprietary drugs is a significant factor in the U.S. health care scheme. Escalating costs of health care create a greater need for low cost self-medication than ever before. Seventy-five percent of all illnesses and injuries are initially treated through self-care and OTC medication. If only a small percentage of self-treatment was shifted to medical practitioners, the patient load would disrupt the U.S. health care system.[1]

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[1] U.S. Department of Commerce, U.S. Industrial Outlook 1978, at 131 (January, 1978).

B. Over-the-Counter Medicines and Tamper-Resistant Packaging

The recent tampering incident in Westchester County, New York, raised for all of us dark memories of the Chicago tragedy in which seven persons died in 1982. The Proprietary Association and the OTC industry committed to the public, to Congress, to the States, and to the Department of Health and Human Services:

-- To place products in tamper-resistant packaging (TRP) as quickly as industrial capacity permitted;

-- To do so with or without legislative requirements;

-- To cooperate with the Department of Health and Human Services and with the Food and Drug Administration in their efforts to establish a national standard requiring tamper-resistant packaging.

That commitment was met. The FDA issued its regulation on the subject five weeks after the Chicago tragedy. During those five weeks, the industry, packaging experts, pharmacists, wholesalers and others cooperated with the FDA to develop the TRP system.

The effort to convert to TRP cost the OTC industry somewhere between $500 million and $1 billion. The result is that today, from a safety standpoint, OTC medicines are the best-packaged consumer goods in the world.

The basic features of the tamper-resistant packaging, and of the federal regulation, are two-fold:

1. That the package have a barrier to entry which, if breached, can reasonably be expected to provide evidence to consumers that tampering has occurred.

2. That the retail package label alert the consumer to the specific TRP feature of the package.

There are eleven forms of TRP commonly used today (Attachment I). Many products have more than one TRP feature. The Association's pamphlet, "Tips Against Tampering," which has received broad distribution, also describes common sense precautions for consumers when they buy and use OTC medicines (Attachment II). Consumer awareness of TRP features and care in buying and using OTC medicines are important elements in the success of any TRP system.

In the period of time since the first TRP rolled out, equipment and technology have advanced, and the TRP and accompanying labeling have become more sophisticated and more effective. But some consumers, particularly the manually or visually impaired, including many senior citizens, have had concerns that TRP was difficult to open. These concerns had to be -- and were -- accommodated. Progress in all areas has continued.

Advances in packaging that have occurred since 1982 include: Specialized tearstrips to permit easier TRP access by the elderly and the physically disabled; increasing use of neck seals with unique, company-specific and product-specific imprinted logos to improve the tamper-evident features; use of more free-flowing glue that will cover the entire flaps of a package and use of more ripable paper stock for outer packages, so entry will be more tamper-evident; use of tapes with distinctive logos across end and side seams of packages; use of shrink wrapping for the entire packaging; changes in the configurations of bottle necks, such as larger neck beads, to achieve stronger bonding of the neck band to make tampering more evident; improvements in "breakaway" caps through use of better materials and design to make them more sturdy during shipping, yet easy to open and tamper-evident; more sophisticated quality control, including production line computer checks to more efficiently evaluate the integrity of seals and reject defective items; and increased use of unit-dosage packaging.

C. Tamper-Resistant Packaging Is Not Tamper-Proof or Criminal-Proof Packaging -- There Is No Tamper-Proof or Criminal-Proof Packaging

When this Association appeared before Congress in 1982 we said "'tamper-proof' packaging is impossible to achieve."[2] And, in issuing its TRP regulations in 1982, FDA stated "the agency stresses that tamper-proof packaging is not possible."[3] FDA went on to say that, in view of that fact, any labeling suggesting that a package is "tamper-proof," as contrasted with tamper-resistant would be considered false and misleading,[4] a violation of the Federal Food, Drug, and Cosmetic Act.

Unfortunately, we do not live in a crime-free society. It is an unhappy fact that good and useful products in daily life are perverted by criminals for use as instruments of terror or murder. We read about them everyday in the newspaper, and we hear about them on the evening news. Rope, pillows, toolbox items, cutlery, glassware, and matchbooks can all be instruments of destruction, and countless consumer products are susceptible to criminal tampering in our free, self-service society. Yet, the risks we face from criminal tampering with OTC medicines are still vanishingly small compared with the risks we face from other anonymous criminal behavior. For example, we understand that in 1984, about 385 people died in arson fires or other suspicious burnings.

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[2] Tamper-Resistant Packaging for Over-the-Counter Drugs: Hearing before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 97th Cong., 2d Sess., Serial No. 97-176 at 33 (1982) (statement of Daniel F. O'Keefe, Jr.).
[3] 47 Fed. Reg. 50444 (November 5, 1982).
[4] Id.

In 1982, our industry was stunned and horrified when a trusted OTC medicine was maliciously perverted to become the instrument of death for seven people in Chicago. The murders are still unsolved. The industry acted immediately, as recounted above, with the result that OTC medicines are now the most safely packaged consumer commodities available. But it is simply impossible to protect society completely from a clever, malicious criminal or insane mind bent on harming the public.

Our industry has been and will continue to be responsive to consumer needs. We are committed to making safe, effective medicines for self-care readily available to the public, at affordable prices. We will respond to this latest challenge.

But, just as there are no burglar-proof bank vaults -- burglars demonstrate that -- there are no tamper-proof or criminal-proof packages for any consumer products, including OTC medicines.

D. The Industry Response to Recent Events

1. Renewed Commitment to TRP

Two working days after the second package of contaminated Extra-Strength Tylenol capsules was reported, the PA's Expert Technical Committee was re-established and met. It consisted of many of the same experts that comprised the group that proved so productive in 1982. As in 1982, representatives of FDA provided information to aid in the Committee's deliberations. (In addition, a technology study subgroup met on Tuesday of this week to review further advances in packaging and dosage forms.)

The Expert Technical Committee reached the following conclusions and made the following recommendations:

1. "Tamper-proof" packaging is impossible to achieve.

2. The tamper-resistant packaging system developed in 1982 remains sound and its success is demonstrated by a

continuing decline in reported tamperings since it was instituted. FDA has told industry that tamper-resistant packaging has proven helpful: Consumers who notice abnormal packaging do not take the medicine, and frequently will report suspicious products to retailers or authorities.

3. The Committee recommended renewed efforts to develop even better technologies to improve the TRP system.

4. The Committee recommended all OTC manufacturers review their security systems for dealing with all aspects of the production and use of tamper-resistant seals and seal material.

The PA Board of Directors met on February 19, 1986, and endorsed all of these conclusions and recommendations.

2. Should the Capsule Be Banned or Its Use Restricted by Legislative or Regulatory Order?

The Expert Technical Committee and PA Board of Directors respect the decision of Johnson & Johnson to drop capsules from its OTC product line. It is recognized that this was a responsible and understandable decision for that company to make under the circumstances.

The Expert Technical Committee concluded that capsules are a valuable and sometimes preferred OTC dosage form, with a long history of safe use. The PA Board endorsed, without dissent, the conclusion to support the continued availability and use of capsules, which play an important role in the delivery of OTC medicines to the consumer.

There are demonstrable benefits to OTC medicines packaged in capsule form:

1. Capsules are easier to swallow than uncoated tablets -- Consumers rate capsules significantly better than uncoated tablets for ease of swallowing, not causing gagging, and no aftertaste -- all of which can contribute to patient compliance with drug regimens. Where a tablet is large, and ingredients may not be able to be coated, and where taste -- even of the coating -- may be important, capsules offer an advantage.

2. Capsules allow enhanced product distinction through use of colors and printing. Product distinction is particularly important in the correct handling of cases of accidental overdose. Accurate and easy -- at a

glance -- product recognition aids patient compliance with drug regimens, and product identification during manufacture.

3. Although not the only type of timed-release formulation, capsules containing encapsuleted beads of active ingredients provide a proven, standardized, and often preferred means to deliver medications safely over prolonged periods, thus enhancing compliance with drug regimens.

4. Capsules tend to sustain less damage during shipping than uncoated tablets, which may chip or break. A chipped product will deliver less than recommended amounts of ingredients, which could affect the product's efficacy.

5. Some medicines do not lend themselves to tablet forms because of the physical effect of the tableting process on the ingredients in the final product form.

6. Capsules mask the smell and taste of ingredients.

7. In a 1983 survey, 54% of consumers said they prefer capsules.[5] In a USA Today poll conducted after reports of the Westchester poisoning, 56% of consumers surveyed said they oppose a government ban on capsules.[6] It is well known that patient acceptance is important to effective therapy. Billions of packages of OTCs are sold annually, and in 1985 about 10.5 billion capsules were used for OTCs in the United States.

Doing away with capsules for OTC medicines would not end the risk of tampering. Absolute protection is not humanly possible. Products in capsule form are no more or less vulnerable to criminal tampering than thousands of other products that Americans buy and use, including OTC medicines in other dosage forms.

We obviously support law enforcement efforts to find the individual or individuals responsible for these heinous acts and bring them to justice. This would be the single best way to deter criminals from tampering with consumer products. Congress itself recognized this by enacting the Federal Anti-Tampering Act in 1983 to make it a federal, criminal offense to tamper with consumer products, with stiff penalties upon conviction.

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[5] Consumer Attitudes Towards Solid Forms of Medication, Burke Marketing Research Study for Capsugel Division of Warner-Lambert Company (March 1983).
[6] USA Today poll, February 21, 1986, p.1.

Our industry will, of course, continue to do its part and devote its efforts to developing improved technologies in manufacturing and packaging. But isolated acts of murder or madness must not dictate how a nation self-medicates by changing a system that has safely delivered OTC medicines to the public for over a hundred years. Society simply cannot operate that way. We do not respond to the arsonist by banning matches or wood or gasoline, and we must not allow a few deranged individuals to eliminate or restrict the availability of an important dosage form of OTC medicine, or we or others will be here again in the future, vainly seeking the criminal-proof product.

CONCLUSION

Over-the-counter medicines are the safest-packaged consumer products in the world, and the industry is dedicated to protecting the integrity of its products and the public health. Technology does not exist, however, that can make any product tamper-proof or criminal-proof. If an individual has the intelligence, the will, and malicious criminal or insane intent, virtually any consumer product (whether drug or other commodity) can be tampered with successfully. Nevertheless, our industry is deeply concerned by the recent tampering incident involving Tylenol capsules, and manufacturers are working to determine if there are ways to make OTC products even more tamper-resistant. The Association and its individual company members shall continue to explore packaging and capsule-sealing technologies, as responsible corporate citizens and as good businessmen. However, banning or restricting OTC medicines in capsule form is not a solution or appropriate reaction to the problem of criminal tampering. FDA has told us that TRP works, and we believe that public education and awareness of TRP features provide the best consumer protection.

Attachment: I -- Eleven Forms of TRP
II -- Tips Against Tampering

DOK/EEB:bws/mee/cc

Attachment "I"

THE PROPRIETARY ASSOCIATION

Expert Technical Committee on Tamper-Resistant Packaging

SOME EXAMPLES OF TAMPER-RESISTANT PACKAGING

Several packaging options are available to provide increased assurance of tamper-resistance of a large number of OTC drugs. Alternate systems which provide comparable margins of assurance are acceptable under the Committee's recommended definition. It is recognized that the state of the art of this technology is evolving.

	PACKAGE TYPE	TAMPER PROTECTION
1.	Film Wrappers	Film wrapped and sealed around product and/or product containers
2.	Blister/Strip Packs	Individually sealed dosage units; removal requires tearing or breaking individual compartment
3.	Bubble Packs	Product or container sealed in plastic, usually mounted on/in display card
4.	Shrink Seals/Bands	Bands or wrappers which conform to cap and container, must be torn to open
5.	Foil, Paper, or Plastic Pouches	Sealed individual packets, must be torn to reach product
6.	Bottle Seals	Paper, foil or plastic sealed to bottle mouth under cap, must be torn or broken to reach product
7.	Tape Seals	Paper or foil sealed over carton flap or bottle cap; must be torn or broken to reach product
8.	Breakable Caps	Plastic or metal caps, parts of which must be damaged or broken to remove
9.	Sealed Tubes	Seal must be punctured to reach product
10.	Sealed Carton	Carton cannot be opened without damage
11.	Aerosol Containers	Tamper-resistant by design

2/27/86

Senator Kennedy's Questions for the Record

PMA/PA

1. On Feb. 18, industry representatives met to consider issues raised by the recent poisoning? Is that right? ANSWER: Yes

2. At that meeting, the continued use of capsules by industry was considered. Is that right? ANSWER: Yes

3. And, it was decided to continue using capsules in their current form?
ANSWER:

Yes, also The Proprietary Association Expert Technical Committee which met on February 18 reached four conclusions and recommendations:

1. "Tamper-proof" packaging is still impossible;
2. The tamper-resistant (TRP) packaging system developed in 1982 is still sound: Its success is demonstrated by a sharp decline in tamperings reported to FDA since it was instituted;
3. Industry should redouble its efforts to develop even better technologies to serve the TRP system now in place; and
4. All over-the-counter (OTC) manufacturers should review their security systems covering all aspects of the production and use of tamper-resistant seals and seal material.

The PA Board of Directors met on February 19 and endorsed all of these conclusions and recommendations.

With respect to capsules, the Expert Technical Committee concluded that capsules are a valuable and sometimes preferred OTC dosage form, with a long history of OTC use. The PA Board endorsed, without dissent, the conclusion to support the continued availability of capsules which play an important role in the delivery of OTC medicines to the consumer.

4. The cost of changing over to another form of medicine was a significant concern? ANSWER: Cost was not discussed.

5. Was the voluntary use of tamper-resistant capsules discussed at that meeting? I understand that there are three tamper resistant capsules on the market. Were they discussed? ANSWER TO PART I: No
ANSWER TO PART II: Sealed capsules were were discussed.

6. What was decided? ANSWER: Although the voluntary use of sealed capsules was not discussed at that meeting, it was the consensus of those present that it would be an inappropriate response for the industry to recommend that government ban or restrict capsules as an OTC dosage form because 1) it would not stop tampering since no dosage form is tamper-proof, 2) it could refocus tampering activity to other OTC dosage forms or other consumer commodities, 3) yielding to criminals would encourage further tamperings and give them authority to decide what products are to be available to the American public and 4) capsules serve a useful and important role in delivery of OTC medicines to consumers.

7. Was the cost a major factor in that decision?

ANSWER: No - Cost was not discussed.

8. The pharmaceutical industry is a highly competitive one, is that right? ANSWER: Yes

9. This competition is even more extreme in the analgesic market. Is that right? ANSWER: The analgesic market is highly competitive. We have no information as to whether or not competition is "more extreme" than in other parts of the industry.

10. Other than the legal suits we know about involving Tylenol, Anicin, and Bufferin over advertising concerns, have companies sued each other in court? ANSWER: While The Proprietary Association does not maintain the type of information, from time to time our members, as in probably all other industries, engage in commercial litigation.

11. To your knowledge, have acts of harrassment ever been carried out by one company against another? ANSWER: No

12. How about acts of sabotage? ANSWER: No

13. Are poisons used in the manufacturing processes utilized by your member companies? ANSWER: No, poisons are not used in the manufacturing process. However, chemical reagents for purposes of quality control, pesticides, and disinfectants are used by companies; these are kept isoldated from the production and packaging of products.

14. Which poisons? ANSWER: This information is unavailable to The Proprietary Association because the types of chemicals used vary from company to company based on individual manufacturing processes and their specific standard operating procedures. However, the chemicals used by companies can generally be found in the United States Pharmacopeia, The National Formulary, and The Merck Index.

15. Are they secured? How? ANSWER: The chemicals used by companies are secured according to the standard operating procedures and practices of individual companies. Some examples include restricted access to manufacturing areas for authorized personnel, locked storage areas, etc.

16. Are there standards for the securing of such poisons? ANSWER: Yes, companies have specific standards which are developed in accordance to Current Good Manufacturing Practices (21 CFR 211). Through the Current Good Manufacturing Practices manufacturers maintain the integrity of their products and this includes the proper securing of chemicals.

17. If not, why not? Not Applicable

18. If so, who wrote the standards? ANSWER: FDA wrote the Current Good Manufacturing Practices. Individual companies write their standard operating procedures for manufacturing which are in accordance to Current Good Manufacturing Practices.

19. Are these standards enforced? How? ANSWER: The PA is not informed concerning the specific enforcement activities of the agencies and companies. But, we understand that routine quality control checks are part of the day-to-day operations of pharmaceutical companies.

20. How often are inspections done in the manufacturing plants?

ANSWER: The Proprietary Association does not know. However, the law requires factory inspections at least once every two years [Federal Food, Drug, and Cosmetic Act; Sec. 510(h), 21 U.S.C. 360(h)]. We are aware that companies conduct their own inspections more frequently.

21. Is the security of poisons or toxins included in what is inspected for? ANSWER: The PA is not aware of the answer to this question. For more information it may be useful to contact inspecting agencies.

22. Who does the quality control in the factory?

ANSWER: Generally, the quality control department.

23. Please describe the FDA requirements for quality control.

ANSWER: The FDA requirements for quality control are described in 21 CFR 211 (a copy of which is enclosed). For more information, it may be useful to contact FDA.

24. Do individual companies have much discretion about how they conduct their quality control? ANSWER: Essentially, no. The basics of quality control are dictated by FDA. Many companies have their own quality controls to supplement those of FDA.

25. Have there been other instances that may not have received so much attention of tampering either with prescription or over-the-counter drugs? ANSWER: Yes, there have been reports of consumer good tamperings including over-the-counter medicines as well as other consumer goods. For more information, you may wish to contact FDA.

26. Have such acts been directed at your member companies at any time in the past? ANSWER: Yes on rare occasion.

27. Are prescription drugs any more or less vulnerable to this type of tampering? Why?

ANSWER: To the dedicated tamperer, no. There is adequate exposure of products along the distribution chain (manufacturing plant; manufacturers' warehouse; wholesalers; chain distribution centers; and retail storage). This point was made by FDA Commissioner Young at the Committee hearing where he stated in answer to Senator Kennedy's question about prescription drugs, "We have no incidents of tampering with the prescription drug supply, but the distribution chain would be similarly vulnerable in prescription as it is in OTC."

28. Do we need additional measures to protect prescription drugs?

ANSWER: No, not at this time.

29. What additional efforts are you planning to make your products more secure? ANSWER: The Expert Technical Committee concluded that industry should redouble its efforts to develop even better technologies to serve the tamper-resistant packaging system now in place. To this end a Technology Study Group has been formed and is currently studying state of the art technology in tamper-resistant packaging and dosage form.

30. How has the current poisoning affected your member companies?
ANSWER: PA member companies are obviously concerned about the recent tamperings and are currently reviewing what can be done to make their products even more secure.

31. In your view, have the resources allocated to deal with this problem been adequate? FBI? FDA? Local investigators? ANSWER: In our view, yes. It may however be useful to contact these agencies.

32. Is there access to other poisons in the manufacturing processes of your member companies?

ANSWER: A large number of chemicals are used by companies. But as mentioned in the answer to question 13, quality control chemicals, disinfectants, and pesticides used by companies are kept isolated from the production of dosage forms.

The **Chairman**. Let us turn to you, Mr. Fink, and we will conclude with your testimony.

Mr. **Fink**. Thank you, Mr. Chairman. My remarks are brief.

I am Peter R. Fink, president and chief executive officer of R.P. Scherer Corp., in Troy, MI. I am accompanied by Dr. Desmond Davis, on my left, vice president and chief scientific officer of our company.

We are the world's largest manufacturer of gelatin capsules, and the only manufacturer of both types of capsules—two-piece hardshell and one-piece sealed soft capsules.

Thank you for the opportunity to testify this morning.

R.P. Scherer shares the concern of other members of our industry about the incidents that have brought us here today. I want to assure you that we and other manufacturers of capsules continue to work very hard to develop new technologies to further protect the consumer.

We believe capsules have an important continuing role in bringing medication to consumers. But some, including officials of two States, have suggested that restrictions be placed on the sale of capsules. The fact of the matter is, if we removed all capsules, we would not remove the risk of tampering.

The risk of tampering is everpresent in our society, regrettably—in our drugs, food, water, and any number of other areas.

I understand that the members of the committee have been provided with capsule samples of two technological approaches for you to examine, and I will comment about these samples shortly.

I want to concentrate my remarks today on what our company is doing to make capsule products more tamper-evident and tamper-resistant. I want to emphasize that other firms in our industry are offering alternative technologies, so my examples today should be viewed as what is commercially available.

I think we all must recognize that it will be virtually impossible to ever guarantee that we can make capsules or tablets or caplets, for that matter, totally tamperproof. We know we can make capsules even more resistant to tampering, and we can also make it easier to detect incidents of capsule tampering. But no one can guarantee a 100-percent tamperproof food or drug product.

One of the technologies available today uses ultrasonic waves to "weld" together the two-piece capsules, and the other involves a one-piece sealed capsule. Let me explain a little about each.

Following the 1982 Tylenol incidents in Chicago, R.P. Scherer developed a process to fuse the two parts of a hardshell capsule. The weld leaves a visible mark or monogram on the capsule. The green-and-white capsules we distributed earlier are filled with an inert substance. If you take a moment and attempt to try to pull them apart, you will see that tampering with one of the welded capsules could break the seal and result in obvious disfigurement of the capsule. Capsules using this technology have been sold in stores for some time.

Since 1982, there also has been increased interest and usage of one-piece, sealed, soft gelatin capsules that I mentioned earlier. You also have another container with several soft gelatin capsules inside. Soft gelatin capsules are one-piece and hermetically sealed. These capsules are most appropriate for drugs in liquid or paste form and are the easiest to swallow and fastest to digest. The soft gelatin capsules offer the fastest and most accurate form of oral drug delivery, and when combined with tamper-evident and tamper-resistant packaging methods, there is no safer method of oral drug delivery.

As you will note also, these capsules come in different shapes and sizes; some are clear, some are opaque.

Any efforts to pierce the capsule shell, because it contains liquid, would leave visible evidence of the tampering.

When combined with tamper-resistant packaging methods, there is no safer method of oral drug delivery than soft gelatin capsules.

We believe it is vitally important to maintain the capsule as a method of delivering oral medication and as a choice for consumers. Capsules are the most preferred dosage form, and for many, capsules are easier to swallow and are perceived as being more effective. As a result, medication reaches patients who otherwise would not take it.

In summary, restricting the sale of capsules, as some propose, would not remove the risk of tampering. Unfortunately, those risks surround us in many aspects of our daily lives, whether it be in the food or drug area.

We have demonstrated that technologies exist today that add yet another level of safety to capsule products, from the weld-like sealing of two-piece hardshell capsules currently in the marketplace, to the usage of one-piece sealed soft gelatin capsules. Both technologies have been adopted, and those and other approaches are available for more widespread use.

Thank you for your interest, and I will be glad to answer any questions you may have.

The CHAIRMAN. Thank you so much.

I would like to compliment R.P. Scherer, for your efforts, as illustrated by these different types of capsulization products that you have produced. I think you have made good efforts to try and make sure that they are as tamperproof as they can be.

Mr. FINK. Thank you, Senator.

The CHAIRMAN. I just wanted to say that to you.

We will keep the record open for all Senators on this committee to ask questions in writing. Senator Kennedy in particular will submit his questions for the record, and we hope you will answer them as soon as you can.

Let me just ask you, Mr. Cope, so we can clarify a few matters, what level of protection from drug tampering should consumers be entitled to expect from your industry? Are they getting that protection? How should your members give us the necessary assurances, and are you?

Mr. COPE. I think consumers are getting the highest degree of protection that industry and technology can provide, Senator. It is a combination of labeling and packaging and dosage form.

The label tells you what to look for and the tamper-resistant feature says, "Important: Do not buy or use this if the seal that says 'Hatch' or 'Cope' or something on it is disturbed," or if the neck seal around the bottle appears loose or tampered with, or if the mouth seal over the bottle appears loose.

So first, it is labeling. Consumers should read the label of every medicine they use, because the label tells them what to look for. Second, the feature itself. Look at the particular feature; examine it to see if it appears loose or in any way disturbed. And then third, examine the actual contents.

So from the standpoint of packaging and labeling, the things fit in very well.

We are, as I said, reexamining the technologies that have developed since 1982. I have mentioned a list of 18 of them which our expert technical committee and the technology subgroup, along with the FDA, are examining. Each company, as with the witness on my left, is looking to see what further it can do.

We did make, as Dr. Hayes said, a significant jump in safety in 1982. As I said, following that we made other improvements and refinements, and now what we are doing is making incremental gains as we go toward perfection.

The CHAIRMAN. I notice that you have put out this excellent little booklet, "Tips Against Tampering," which is a foldout booklet, where you list inside of here, "Protecting Yourself," "Package Type," description of the package, "Tips for Checking Your Medicines," packages, liquids and tablets, capsules, tubes and jars. It is basically pretty understandable.

Is this being made available on a larger scale.

Mr. COPE. Yes.

The CHAIRMAN. OK.

Now, would absolute protection from tampering be available if the industry and the public were willing to absorb the costs? Could you have an absolute protection, in your opinion?

Mr. COPE. No.

The CHAIRMAN. In other words, you feel you are doing the best you can, that the incidents have come down, and that it is probably impossible to stop the ingenious tamperer or criminal.

Mr. COPE. I think a combination of the five factors that I ended my statement with is the way to proceed. We cannot do it alone, but I think with all of us working together we can narrow it down.

The CHAIRMAN. I think those are good points.

You state in your testimony that there are demonstrable benefits to capsules over tablets. I have been led to believe that as well. How important are these benefits, in view of the fatal tragedies we have been discussing here, particularly in regards to the Tylenol capsule problem?

Mr. COPE. I think that will be decided by the consumers themselves. We are a very intense consumer industry, and if consumers find, as surveys have shown and as we know from our own experience, that capsules offer a plus to them, that they find ease of ingestion, the masking of smell and taste, for whatever reason, sustained dosage forms. If the consumers want them, then I think they will continue buying them on the marketplace. If they leave them in droves, we will all have that message.

The CHAIRMAN. Now, in your written statement, you stated that there has been a continued decline in reported tamperings since the new tamper-resistant packaging approaches were developed in 1982 and thereafter. How sharp a decline are we talking about? Do you have any specific numbers?

Mr. **Cope**. The FDA gave them——

The **Chairman**. So you agree with the FDA.

Mr. **Cope**. Yes.

The **Chairman**. Well, that was a stark decline.

Mr. **Cope**. Yes, quite.

The **Chairman**. And I think that is one thing that the listening public should be interested in as well.

Could you provide the committee with some details of the tamperings that have occurred since 1982, and what injuries people have suffered, if any?

Mr. **Cope**. I think that would best come from FDA.

The **Chairman**. All right. We will ask them to do that.

Now, you state that capsules tend to sustain less damage in shipping than uncoated tablets, and that a chipped product will deliver less than the recommended amounts of ingredients.

Now, by what percentage does chipping affect the product's efficiency? That would be assuming the product is properly packaged.

Mr. **Cope**. I think that is a function of how big the chip is. That is more of an economic point, and we do not hold that out as a major one.

The **Chairman**. All right. That is good to know.

I want to thank you for coming. I think that this hearing has been a very good hearing. A lot of people are very concerned about what is happening, and I think the witnesses from beginning to last have alleviated a number of those concerns, even though we all have to be concerned about this type of vicious conduct in our society.

I am interested in asking each of you to consider whether Congress needs to get even tougher criminal laws on the books and to enforce them in a better manner, although I do believe the law enforcement agencies are doing the best they can.

Anything else that industry or consumer groups, Government or otherwise, can come up with that might be able to help resolve these problems and make all consumer products safer we would be happy to have your advice on.

We do commend you for the excellent work you do. We know that you take this seriously, and we just want you to know that we have appreciated your testimony here today.

[Additional material submitted for the record follows:]

Statement of the American Pharmaceutical Association

The National Professional Society of Pharmacists

ON DRUG PRODUCT TAMPERING
PRESENTED IN CONJUNCTION WITH THE
HEARING OF FEBRUARY 28, 1986
HELD BY THE
SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES
U.S. SENATE
WASHINGTON, D.C.
MARCH 10, 1986

American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, D.C. 20037

(202) 628-4410

The American Pharmaceutical Association (APhA) is the national professional society of pharmacists, representing the third largest health profession comprised of more than 150,000 pharmacy practitioners, pharmaceutical scientists, and pharmacy students. Since its founding in 1852, APhA has been a leader in the professional and scientific advancement of pharmacy and in safeguarding the well-being of the individual patient and the American Public. Therefore, APhA is especially appreciative of the opportunity to provide this statement of the Association's views on the current crisis involving drug product tampering.

Like all who are deeply concerned about this problem, APhA is distressed and saddened by the fact that the American Public has had to endure this trying experience so soon after a similar occurrence just over three years ago. As in 1982, the nation's pharmacists and their national professional society, APhA, share with the American people a sense of shock and outrage over the recent poisoning of Tylenol capsules that has resulted in yet another fatality.

As in the past incident, APhA commends the responsible and reasoned responses that have been exhibited by all involved--the

Johnson & Johnson Company, McNeil Consumer Products, the Food and Drug Administration, the Proprietary Association, the U.S. Congress, and to a large extent the print and broadcast media. And APhA is especially proud of the nation's pharmacists, who, along with other health care professionals, have similarly reacted to this public crisis with responsiveness and cooperation.

Immediately upon being notified of the current crisis, APhA developed the following strategy to provide guidance to the profession on how the nation's pharmacists might best assist in protecting the health of Americans from such tragedies:

1. The American Pharmaceutical Association should use its available media resources to publicly restate the Association's confidence in the integrity of today's pharmaceutical products. Recognizing that it is currently impossible to produce tamper-proof packaging, the Association should commend the pharmaceutical industry for its continued technological improvements in this field, and it should offer to work with the pharmaceutical industry to further explore improved alternatives to tamper-resistant packaging.

2. The Association should join with the pharmaceutical industry to produce a mutimedia public education campaign. This campaign should promote the role of the pharmacist as a public education source regarding the nation's drug supply, drug distribution system, and drug product packaging. The ultimate goal should be to bolster public confidence in pharmaceutical products and to reduce the consumer's chances of purchasing a tampered product.

3. The Association should strive to better educate pharmacists about drug product tampering. Specificly, an article should be published in American Pharmacy (APhA's monthly journal) that discusses the latest technology in tamper-resistant packaging.

4. To keep pharmacists informed on this issue, invite McNeil Consumer Products and other pharmaceutical manufacturers to publish relevant articles in American Pharmacy.

Immediately following release of the news of the current crisis, APhA representatives were involved in a number of contacts with members of both the print and the broadcast media, and APhA officials appeared on two nationally-broadcast television programs to apprise the public of the Association's view of the problem and to help alleviate the public's fears and anxiety. APhA also held extensive discussions with senior FDA officials to offer information, advice, and support. We also immediately provided information to our members and to the profession through our own publications and the issuance of a widely-distributed news release.

Other actions implementing the APhA strategy are also under way. For example, in an effort to bring more information to the public, APhA has joined with the Pharmaceutical Manufacturers Association to develop just the kind of multimedia public relations campaign that the panel has recommended. The campaign will serve to assure the public of the integrity of the nation's drug supply, emphasize the cost-benefit advantages of medications, and focus on the enhancement of their effectiveness which is gained through the involvement of the pharmacist in the management of their proper use. The Association has also begun preliminary discussions with the Food and Drug Administration regarding the possibility of the joint development of a public education campaign involving the nation's pharmacists which would focus directly upon the drug product tampering problem.

APhA also is stepping up its efforts to educate pharmacists about the drug product tampering problem and the role that they can play in directly guarding against tampering incidents and in educating the members of the public about actions that they can take to combat the problem. A comprehensive article addressing these issues is already scheduled to appear in an upcoming issue of the Association's journal.

Finally, APhA is confident that the industry will continue to be responsible and responsive in addressing this problem competently without further urging or requirement to do so by government, the professions, or the public. In that spirit, APhA pledges its full cooperation and that of the nation's pharmacists in the development and implementation of any voluntary measures that will assure the continued integrity of the nation's drug supply and the protection of the American Public.

February 26, 1986

The Honorable Orrin Hatch
135 Russell Building
Washington, D. C. 20510

Dear Senator Hatch:

We have been made aware that you are holding Congressional hearings regarding the recent attack against Johnson & Johnson and their product Tylenol.

We recognize the critical importance of such fact-finding hearings and respectfully request to submit information to you and your committee that directly affects our business and our industry. As manufacturers of one-piece heat sealed Soft Elastic Gelatin capsules, Banner Gelatin Products Corp., Encapsulations, Inc., and Pharmacaps, Inc. wish to submit information clarifying the specifics of our unique product technology. Ours is a small segment of the solid oral dosage form category, but it is one of extreme importance in providing a technologically superior dosage, most particularly for liquids, liquid emulsions, and past medicines.

Unfortunately, in the rush to expedite coverage of the Tylenol situation, the media has neglected to differentiate between the one-piece Soft Elastic Gelatin capsule and the two-piece hard shell gelatin capsule that suffered the tampering incident. A simple analogy might be that hard shell capsules and one-piece Soft Elastic Gelatin capsules are like apples and oranges; they are both fruits but of distinctly separate varieties.

As one-piece Soft Elastic Gelatin capsules are manufactured in one continuous flow process, that is to say the capsules are formed, filled, and sealed all in one operation, they are far less susceptible to the possibility of tampering as it in fact becomes a unique sealed container in and of itself. Further, the characteristics of the Soft Elastic Gelatin capsule are such that any attempt to invade its shell results in an obvious physical and visual tamper-evident state.

Quite candidly, our concern is that our industry is being unduly damaged by the undefined and inadvertent inclusion of one-piece Soft Elastic Gelatin capsules with two-piece hard shell capsules. The F.D.A. summarized in the Federal Register in 1983 that one-piece Soft Elastic Gelatin capsules are less susceptible to tampering than two-piece capsules.

In closing, we wish to state that we are saddened by the unfortunate circumstances surrounding Johnson & Johnson but feel that patience, commitment, and responsibility can resolve the tampering of any product with more security to the consumer. I thank you for your concern and consideration in recognizing the unwarranted jeopardy our industry finds itself in.

Respectfully,

Gordon Freshman

Gordon Freshman, President
Banner Gelatin Products Corp.

Jack Gilbert

Jack Gilbert, President
Encapsulations, Inc.

Lionel Borkan

Lionel Borkan, President
Pharmacaps, Inc.

POSITION PAPER

"ONE-PIECE HERMETICALLY SEALED SOFT ELASTIC GELATIN CAPSULES"

Submitted February 28, 1986

To

The Honorable Orrin Hatch,

Chairman of the

Labor and Human Resources Committee

Submitted by:

Encapsulations, Inc.,
280 Chestnut Street
Newark, New Jersey 07105

Pharmacaps, Inc.,
1111 Jefferson Avenue
Elizabeth, New Jersey 07207

and

Banner Gelatin Products, Corp.,
20730 Dearborn Street
Chatsworth, California 91311-0230

POSITION PAPER

Recent occurances involving adulteration of over-the-counter pharmaceutical products with hazardous materials have again initiated considerable discussion at both industry and governmental levels regarding improvement of tamper-resistant and tamper-evident packaging.

In this submission, we wish to offer technical information regarding the heat-sealed one-piece soft Elastic Gelatin capsule.

We further suggest it be considered as a viable alternative to other solid oral dosage forms to utilize its superior tamper resistant and tamper evident characteristics.

ONE PIECE CAPSULE

As a result of the fact that the soft gelatin capsules are manufactured in one continuous operation, in which heated gelatin mass is formed into capsules and injected with a base containing the active ingredients on a specialized rotary-die encapsulation machine, the capsules are hermetically sealed. In addition to being tamper-resistant, the sealed capsule has the added advantage of preventing microbial contamination and oxidation of actives.

UNIT DOSE

The hermetically sealed one-piece soft elastic gelatin capsule, is a packaged unit dose. Product contamination is avoided, since actives are protected by the gelatin shell. Its convenience is matched by its versatility. For example, if a solution, a teaspoon is not required - if it is a suppository, refrigeration is not necessary to prevent it from melting.

UNIFORMITY IN DOSAGE

The active ingredients to be encapsulated are either in solution or suspension. The production operation required to dispense a unit dose of liquids or semi-liquids into capsules is much more precise than for a solid fill. Also, a solution or suspension has much greater uniformity than a solid mixture and, therefore, provides greater product uniformity.

Preparation of the blend to be encapsulated - that is the actives and the base serving as a vehicle - is very much different from the blends for tablets and two-piece hard capsules. Soft gelatin capsules incorporate liquids or semi-liquids; tablets and hard capsules are comprised of solids. Uniformity can be obtained in a solution, by definition, and in a suspension by adequate mixing. Uniformity achieved by mixing solids is much more difficult and is not reached as effectively as with liquids or semi-liquids. Factors that must be considered in mixing solids include particle size distribution, densities, particle shape and efficiency of mixing equipment.

ACCURACY IN DOSAGE

Active ingredients that require minute dosage can be encapsulated with high precision. The actives are carried in a liquid base so that a small dose contained in a larger volume of liquid can be dispensed accurately. For example, oral contraceptive tablets can contain a very low level of estrogen, approximately 50 to 100 micrograms per tablet. Conversely, the content uniformity in tablets is not nearly as reproducible with high levels of actives, because small amounts of actives will not be dispersed to perfect homogeneity in the blend. Due to the effect of a very low ratio of active weight to total weight, any flaw in accuracy will be exaggerated.

IMPROVED STABILITY

The shell protects the actives from air, light, moisture and reasonable temperature variations and active ingredients are subsequently subjected to less deterioration each time the container is opened to remove a single dose. Because the stability of actives in a soft gelatin capsule is generally superior, the unit dose can sometimes be reduced.

IMPROVED BIOAVAILABILITY

Active ingredients are released in liquid form for rapid dispersion as soon as the gelatin shell opens. Complete disintegration and dissolution are not necessary for actives to be available. Also, certain relative insoluble actives can be dispersed in a liquid medium to provide faster absorption.

Dissolution and bioavailability of some drugs in soft gelatin capsules has been shown to be superior to two-piece hard capsules, tablets and solutions (1-4).

This has been demonstrated in:

. Digoxin
. Digitoxin
. Chloramphenicol
. Nitrofurantoin
. Prednisolone
. Phenylbutazone
. Hydrocortisone
. Ethynylestradiol
. Diethylstilbesterol
. Phenobarbital
. Reserpine
. Bishydroxycoumarin

Studies have shown that availability for absorption of a drug is generally the least for coated tablets and then increases for compressed tablets, powder-filled two-piece hard shell capsules, suspensions - to the best bioavailability in solutions (2). One-piece soft gelatin capsules contain solutions or suspensions. Dissolution from soft gelatin capsules has been demonstrated as being generally faster than the dissolution rate from tablets. In addition, the increase in amount of actives dissolved from soft gelatin capsules ranged from 1.1 to 400 times that of tablets. In another study (1), digoxin absorption was shown to be more rapid and complete from soft gelatin capsules than from tablets, hard capsules or an oral solution. Additionally, two-piece hard gelatin capsules and tablets require additional manufacturing operations that may alter the bioavailability characteristics of the product and also the batch uniformity - i.e., coating, granulation and compression.

EASE OF APPLICATION

Soft gelatin capsules are smooth and soft for ease of administration orally, rectally or vaginally. Soft gelatin capsule tubes are available for topical and cosmetic application in the correct quantity from a disposable capsule tube.

A DIFFERENT DOSAGE FORM

We have reviewed one-piece hermetically sealed soft elastic gelatin capsules as a solid oral dosage form that is unique and different from other such dosage forms. The soft gelatin capsule has more than one method of administration in that it can be shaped to an oval, round, oblong, tube or suppository. The gelatin capsule or shell serves as a container for the active ingredients which are either in solution or suspension. The capsule fill material, containing the actives, is a solution or paste. Bases that are utilized must be compatible with gelatin and include vegetable and mineral oils as water immiscible carriers or the polyethylene glycols as water miscible carriers. There is a good deal of latitude to select a base that will solubilize an active that may otherwise be insoluble. Aids such as surfactants and solubilizers can be incorporated into the base also. In addition, many colors, shapes and sizes are available.

Soft gelatin capsules can be utilized to encapsulate a variety of products. Oval, round and oblong shapes are ideally suited for oral administration. Tubes are designed for topical application or for oral administration in infants. Suppositories are intended for rectal or vaginal application. Formed into different shapes depending on the mode of actives administration, the hermetically sealed gelatin container represents many practical applications of a dosage form.

Just as there are many types of product available in soft gelatin capsules, there are several product categories applicable. Pharmaceuticals include human and veterinary, over-the-counter and prescription. Nutritional supplements are a second category. Cosmetics are a third category and household and industrial products another.

Conclusion

It is important also to consider consumers and the preferences that they have in dosage forms. The manufacturer does have a responsibility to select the best dosage form for a product that matches consumer demand. A survey conducted recently by Opinion Research Corporation, a division of Arthur D. Little, compared one-piece soft gelatin capsules to two-piece hard capsules and tablets in sales and consumer preference (5,6). Soft gelatin capsules were reported to control only 2% of the market in units sold, but, most importantly 44% of consumers preferred this dosage form.

Many alternatives are being considered to provide tamper-resistant packaging. One-piece hermetically sealed soft elastic gelatin capsules offer technical flexibility in a tamper-resistant and tamper-evident dosage form.

As noted above, there are many such positive attributes to this unique sodage form, most importantly, maximum product safety.

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The **Chairman**. Thank you so much, and with that, we will recess until further notice.

[Whereupon, at 1 p.m., the committee was adjourned.]

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